

出國報告（出國類別：實習）

參加新加坡航空人員證照稽查技巧班
及執行中華航空公司（桃園-新加坡）
國際線駕駛艙航路查核
出國報告書

服務機關：交通部民用航空局

姓名職稱：賴治民（約聘人員）

黃曉荼（約聘人員）

派赴國家：新加坡

出國期間：101年10月28日至11月1日

報告日期：102年1月8日

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壹、目的

航空人員依民用航空法之定義係分為航空器駕駛員、飛航機械員、地面機械員、飛航管制員、維修員及航空器簽派人員等六類，並依法規賦予之職權執行各項業務，故航空人員之養成對於飛航安全有直接關鍵性的影響。本局除對航空人員進行檢定、給證等管理作為外，為使航空人員專業技術與學識能跟隨日新月異之航空科技不斷進步，並確保訓練成效，對於訓練養成機構也必需進行相關規範管理。

民航局每年均有規劃查核計畫，並依預劃派遣航務、適航檢查員至民航業者檢查各項人員、訓練及設備，並督導其業務，如有缺失，則通知受檢者限期改善。另目前國內經核准之訓練機構包含僅得以實施飛航駕駛員地面學科之「飛亞航空訓練中心」及「華夏飛航訓練中心」，以及培育地面機械員之「中華科技大學航空維修教育訓練中心」訓練機構。

本次課程由新加坡航空學院(SAA, Singapore Aviation Academy)舉辦，課程內容旨在提供學員有效規劃與執行訓練機構及人員證照安全稽核之原則與技能。本次研習行程另由本局航務檢查員賴治民分別於 101 年 10 月 28 日及 11 月 1 日執行中華航空公司桃園-新加坡國際航線往返之駕駛艙航路查核。

貳、過程

日期	行程 / 課程
10月28日	由桃園搭乘中華航空公司航班前往新加坡，兼施國際航線駕駛艙航路查核。
10月29日	<p>新加坡航空學院第一日課程：</p> <p>(報到與開幕式)</p> <ul style="list-style-type: none"> ● Structure and key elements of Part FCL Group Discussion ● Contribution of Suppliers Process Modeling ● Regulatory Approval & Oversight of TRTOs and FTOs ● Regulatory Oversight & Internal Auditing Introduction to practical audit activity
10月30日	<p>新加坡航空學院第二日課程：</p> <ul style="list-style-type: none"> ● Audit Planning Methodology Syndicate Exercise ● Developing High Level Check Lists Evidence finding ● Syndicate Exercise ● Interview and Questioning Techniques Psychology of Audit

- 10月31日 新加坡航空學院第三日課程：
- Practical Auditing Activity Part 1
 - Practical Auditing Activity Part 2
- Preview of Audit Activities
- Syndicate Exercise
- Review of Nonconformity Statements
- Audit Reports
- Corrective Action
- (閉幕式)
- 11月1日 由新加坡搭乘中華航空公司航班返回桃園，兼施國際航線駕駛艙航路查核。
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參、出國內容摘要

一、新加坡航空人員證照稽查技巧班：

(一) 學習摘要：

新加坡航空學院為新加坡民航局之所屬訓練單位，訓練範圍包含航空管理、民航安全與保安、航空交通管制及機場緊急救援等四大領域，主要提供新加坡國內和亞太地區航空專業人士相關進修培訓課程。

本次講師提供之課程教材如附件一及附件二。講師因考量授課期間僅有三日，遂依教材設計每日課程，課堂以分組討論、實例分析為主教材授課為輔，茲將講習主題分為三大部分：

課程日期	講習主題
10月29日	稽核(audit)、相關名詞(terminology)與模式(model)之定義，以及國際法規依循標準。
10月30日	稽核程序設計以及事實記錄技巧與分析
10月31日	分組討論實際稽核模擬演練。

透過本次的學習，學員更能了解完整的稽核流程，並完成有事實依據具有公信力之稽核報告。透過講師 Capt. Brian Dermot Brophy 於課堂上之引導與經驗分享，學員可進一步了解受稽核者(auditee)之心理壓力，藉此學習稽核人員(auditor)應具備之內在特質與態度，以取得互信之基礎；期使日後於執行業務時，當稽核人員發現缺點事實後，受稽核者不致於排斥甚至尋求民意代表及媒體等管道抵制，且願意配合改善，以具體提昇飛航安全品質。

(二) 課程參與人員：

單位(國籍)	姓名	職稱
課程講師 CHC Ireland Ltd. (愛爾蘭)	Brian Dermot Brophy	Type Rating Examiner / Synthetic Flight Examiner

民航局(R.O.C)	賴治民	航空安全檢查員
民航局(R.O.C)	黃曉荼	航空人員證照行政
PACA-Oman (安曼)	Sara Ali Al Owaisi	Licensing Inspector
CAMA-Yeman (葉門)	Almadani, Khalid Ali M.	Manager of PEL
CAAS, Singapore (新加坡)	Chan, Yi-Xiang	Assistant Manager
Asian Academy of Aeronautics, Republic of Maldives (馬爾地夫)	Suranjan De Silva	CEO & Head of Pilot Training
State Secretariat of Civil Aviation, Cambodia (柬埔寨)	Lim Kao	Director

二、中華航空公司（桃園-新加坡-桃園）國際線駕駛艙航路查核

（一）搭乘航班：

日期	航空公司	航班編號	航段	時間(UTC+8)
10月28日	中華航空公司	CI-753	桃園→新加坡	07:30-16:45
11月01日	中華航空公司	CI-754	新加坡→桃園	12:50-18:30

（二）10月28日去程：

去程由機長許建偉及副駕駛員吳明遠執行本班次任務，檢視駕駛員均攜帶體檢證及檢定證，且於有效期限內。本航班由機長擔任操控飛行員(以下簡稱 PF, Pilot Flying)，飛行前各項資料準備完整，然於航機完成開車及後推時，機長發現航機儀表出現系統異常訊息” F/CTL AIL SERVO FAULT”，並按照 QRH(Quick Reference Handbook 快速參考手冊)及 MEL(Minimum Equipment List 最低裝備需求手冊)執行應變處置措施，機長與華航修護單位查閱手冊規定及討論後，決定自行滑回停機坪並更換飛機零組件，同時機長於適當時機為乘客作廣播。經檢修完成航機簽放後，機長執行第二次開車程序後，航機恢復正常運作。本次航機異常事件導致原定 0755 時起飛班機因而延誤約 4 小時。觀察其他飛航階段執勤情形，駕駛員皆按規定以檢查表執行各項檢查程序，協調合作良好，遇不穩定氣流時，駕艙組員並按程序適時與客艙組員聯繫，以確保乘客之飛航安全。

(三) 11 月 01 日回程

回程受來機晚到及機場流量管制影響，班機延遲 30 分鐘起飛。由印尼籍機長 Eddie Pramono 及副駕駛員陸天瑢執行本次飛航任務，檢查組員及飛機各項證照均具備且於有效期限內。於各階段飛行中，組員均依檢查表執行各項檢查，在滑行時與起飛前，均依照航管單位指示，對於跑、滑道方向行

徑路線確實按圖進行，組員協調合作良好，組員於航路飛航時遭遇雷雨或上下對流旺盛之積雨雲，能善用氣象雷達回波，於航機抵達前均能適時避讓，確保客艙內乘客及客艙組員之生命安全，駕駛員整體飛行計畫及操控飛機情況均屬正常。

肆、心得與建議

系統稽核可透過人員訪談、手冊紀錄之資料收集以及實地觀察等，了解缺陷或事件發生的原因，並提出改善建議，受稽核/調查之單位並需對此提出相對應、有效及可接受的改正措施。因稽核範圍受限於稽核單位規模大小以及時間等限制，故事前準備工作、以及稽核時文件檢查及人員訪談的採樣技巧，便成為稽核成敗的關鍵。本訓練除就稽核理論加以解說外，更包含分組討論及情境模擬，讓學員彼此學習交流，並於小組分享時由講師適時引導說明，使學員更能身歷其境地體驗稽核可能遭遇到的問題與解決方法。

安全稽核為安全管理系統中持續改善飛航安全之重要一環，此課程所講授之安全稽核技巧雖重點在於航空人員證照及航空訓練機構稽核，但稽核理論、技巧與實務大致相同，亦可套用至民航運輸業/普通業檢查員制度。若能持續依據安全管理系統 Plan、Do、Check、Act 之模式，應用於稽核之相

關技巧，當能持續有效監理航空業者。本次受訓能立即將所得學以致用，建議可視需要賡續派員至新加坡航空學院選訓諸如稽查或航空檢查之相關課程，期使更有效率管理航空業者、提升本國飛航安全。

伍、附件

附件一：Auditing in Relation to Flight Crew Licensing

附件二：Regulatory Approval and Oversight



Auditing in Relation to Flight Crew Licensing



**Auditing in relation to
Flight Crew Licensing**

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TERMINOLOGY (Not definitions):

Audit

A term used to describe the physical examination of actual practice, or the results achieved, for an activity and the comparison with requirements detailing what should be done and how it should be done, or the results that should have been achieved.

Audits are not undertaken to verify that actual practice, or an item, is acceptable in order to allow continuation of the process. Audits are undertaken in order to provide unbiased objective data to enable judgements to be made about the overall acceptability of a system, process or product.

Auditing is primarily a feedback mechanism for the purpose of providing confidence that a process or system is capable of providing acceptable outputs or outcome.

System / Process / Product Audit

Audit to verify the effective implementation of a system / process or that a product complies with requirements.

Internal Audit

Audit undertaken by an organisation on its own system, process or product.

Compliance Audit

An audit conducted to verify that a product or process complies with requirements.

Audit client

Organisation or person requesting an audit and requiring the audit information.

Audit criteria

Set of policies, procedures or requirements that the auditor is verifying conformity with.

Audit findings

Facts obtained by the auditor indicating conformity or nonconformity with the audit criteria.

Audit Scope

Those parts of the organisation that are to be subject to audit activity.

Auditee

The organisation or person being audited.

Auditor

A person with the authority to undertake an audit.

Inspection

The true meaning relates to the physical inspection of a tangible item for the purpose of verifying that it meets the specified requirements, and is suitable for continued processing or delivery.

Note: The term "inspection" is often applied to the activities undertaken by a regulatory 'inspector'. This activity is better known outside aviation as "Audit".

Nonconformity

A generic term used to describe the factual evidence that indicates that there is a situation that does not meet specified requirements.

Noncompliance

A term used to describe the factual evidence that indicates that there is a situation that does not meet regulatory requirements.

Objective evidence

Evidence that exists such as records, or other information including observations. (*Statements made are not objective evidence*).

Quality

A totality of features or characteristics of a product / service that satisfy customer requirements / expectations, or is fit for the intended use. (*Good quality implies features and characteristics that meet defined requirements*)

Safety

An intrinsic property of a product / service or of a system.

Assurance

The means of providing confidence that a management system is being implemented effectively and that requirements will be met. (The term 'Assurance' may be linked to a management system focusing on quality, when it is termed "Quality Assurance", however it may also be linked to Safety when it may be termed "Safety Assurance")

Quality Control

Mechanisms used, such as checks or tests, that are performed to ensure that requirements are met.

Management System

The means by which an organisation manages its activities to achieve its objectives.

Objective

A specific target that management wish to meet. This could be in relation to Safety, Quality, Environmental performance, etc.

Policy

A statement setting out the overall intentions of an organisation in relation to the delivery of products / services meeting specified requirements (relating to overall standards to be achieved, intrinsic safety etc.).

Management Systems & Compliance Monitoring

Management Systems - Basic Principles

Documenting and Communicating the System

Contribution of Suppliers

Compliance Monitoring

Management System Review

Management Systems - Basic Principles.

Many regulations are now requiring organisations to adopt more formalised and systematic approaches to managing their aviation related activities with recognition that the intrinsic ability of an organisation to effectively manage itself is likely to have a direct effect on safety performance. In particular there is often a requirement for an organisation to put in place a "Management System" and although guidance material is available to explain what is meant by the terminology, difficulty may still be experienced in understanding the concepts and in knowing what is required in order to put in place a "Management System" that is deemed to be satisfactory.

What is a "Management System"?

An organisation has a desire to meet certain objectives. These objectives may relate to regulatory compliance, the provision of products and/or services to specified standards, business efficiency, the meeting of financial targets, return on investment for shareholders, growth, etc.

Normally for a commercial organisation there will be the realisation that growth and shareholder satisfaction will be heavily dependent upon overall efficiency and the ability of the organisation to attract and retain customers. Attracting and retaining customers will require the organisation to focus on quality, and to manage any influences that could give rise to adverse effects relating to the product / service provided. Such influences could relate to Safety, Environmental impacts, etc. for which there could also be regulatory requirements.

Non-commercial organisations may have a similar need to manage effectively in order to achieve objectives, set either by the organisation itself or by higher authorities.

A management system is the means by which an organisation plans and manages its activities in order to meet its objectives, which in turn act in support of an overall business policy.

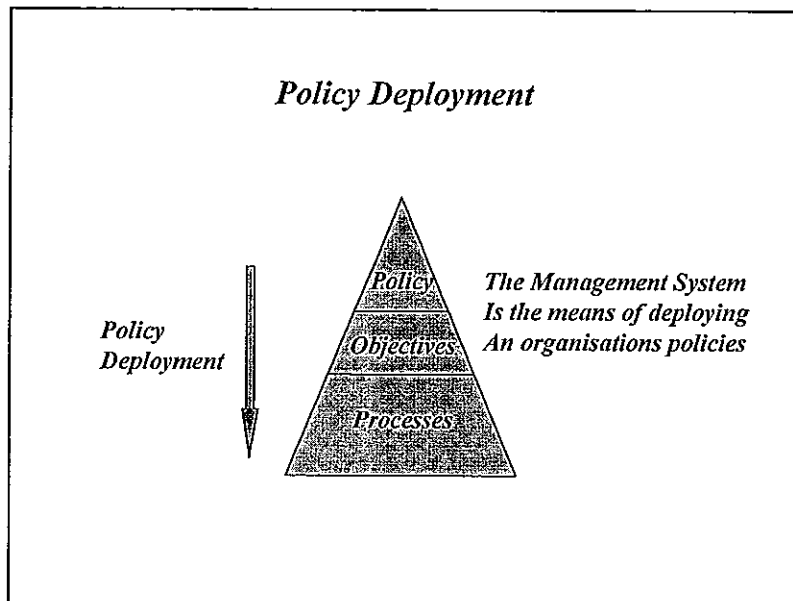
Management Systems

A "Management System" is the means by which an organisation plans and manages its activities in order to meet its objectives.

A collection of "processes" that an organisation puts in place and needs to manage effectively in order to achieve its organisational objectives.

Process based management systems.

Activities undertaken in an organisation are usually referred to as 'Processes' and a management system is simply a collection of processes that the organisation needs to put in place and manage effectively in order to achieve its organisational policy and associated objectives.



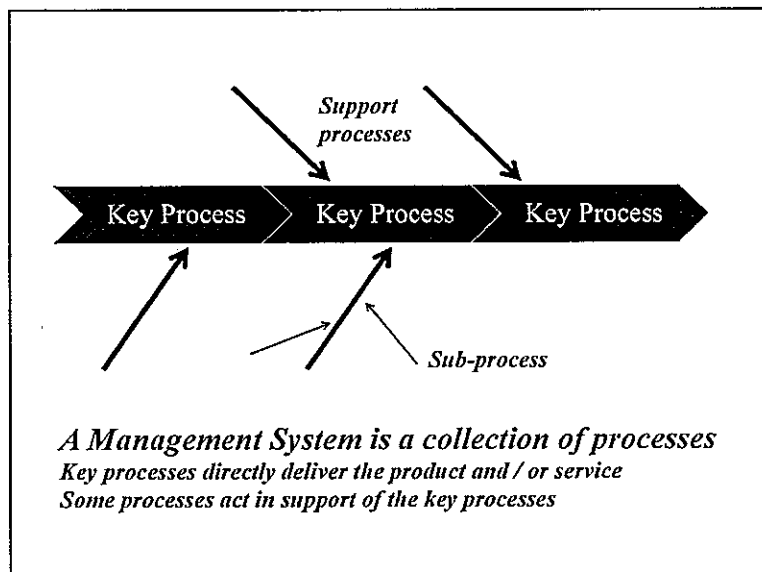
There is no point in the management of an organisation putting in place a high level policy, relating to safety etc. unless they are also prepared to develop a management system that will act to ensure that the policy is 'deployed' throughout the organisation at all levels and with all personnel. The management system will need to be carefully determined to suit the needs of the organisation, not only to act in support of the high level policy but also taking into consideration the material resources available, the cultural environment and the needs of operational and support staff.

A management system will be unique to a particular organisation, and it is wrong to assume that what might be suitable in one organisation will also be suitable in another. There is also a distinct difference between 'process' and 'documented procedure'. Processes need to be designed to enable specific objectives to be achieved, they may or may not require one or more procedures to ensure that the process is implemented effectively.

"Key" processes are normally considered to be those processes that deliver the product and/or service to the customer, whereas support processes are those processes that facilitate or support the key process. However, key processes could also be considered to be those that are particularly related to the intrinsic safety of the product and/or service. There may be several 'key' processes that link in a sequential way to provide the organisations product and/or service, and there may be very many support and sub processes that are necessary to enable the key processes to function effectively.

An example of a 'Key' process is the delivery of a training course.
An example of a support process is a 'Document Control' process.

With process based management systems there is recognition that processes must be carefully designed to ensure effective operation of the process and adequacy of process outputs. Process performance and outputs need to be monitored and where necessary improved to ensure meeting an organisations objectives.



Part Ops requirement for a "Management System"

ORO.GEN.200 Management system

(a) The operator shall implement and maintain a management system that includes:

(1) clearly defined lines of responsibility and accountability throughout the operator, including a direct safety accountability of the accountable manager;

(2) a description of the overall philosophies and principles of the operator with regard to safety, referred to as the safety policy;

(3) the identification of aviation safety hazards entailed by the activities of the operator, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness;

(4) maintaining personnel trained and competent to perform their task;

(5) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;

(6) a function to monitor compliance of the operator with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary;

(7) any additional requirements that are prescribed in the relevant subparts of this Part or other applicable Parts.

(b) The management system shall correspond to the size of the operator and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.

The "Management System" requirement should be read in conjunction with the following:

ORO.GEN.205 Contracted activities

(a) Contracted activities include all activities within the operator's scope of approval that are performed by another organisation either itself certified to carry out such activity or if not certified, working under the operator's approval. The operator shall ensure that when contracting or purchasing any part of its activity, the contracted or purchased service or product conforms to the applicable requirements.

(b) When the certified operator contracts any part of its activity to an organisation that is not itself certified in accordance with this Part to carry out such activity, the contracted organisation shall work under the approval of the operator. The contracting organisation shall ensure that the competent authority is given access to the contracted organisation, to determine continued compliance with the applicable requirements.

ORO.GEN.210 Personnel requirements

(a) The operator shall appoint an accountable manager, who has the authority for ensuring that all activities can be financed and carried out in accordance with the applicable requirements. The accountable manager shall be responsible for establishing and maintaining an effective management system.

(b) A person or group of persons shall be nominated by the operator, with the responsibility of ensuring that the operator remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the accountable manager.

(c) The operator shall have sufficient qualified personnel for the planned tasks and activities to be performed in accordance with the applicable requirements.

(d) The operator shall maintain appropriate experience, qualification and training records to show compliance with paragraph (c).

(e) the operator shall ensure that all personnel are aware of the rules and procedures relevant to the exercise of their duties.

ORO.GEN.215 Facilities requirements

(a) The operator shall have facilities allowing the performance and management of all planned tasks and activities in accordance with the applicable requirements.

ORO.GEN.220 Record-keeping

(a) The operator shall establish a system of record-keeping that allows adequate storage and reliable traceability of all activities developed, covering in particular all the elements indicated in ORO.GEN.200.

(b) The format of the records shall be specified in the operator's procedures.

(c) Records shall be stored in a manner that ensures protection from damage, alteration and theft.

Quality Management Systems.

A Quality Management System is a collection of processes aimed at the provision of products and / or services that satisfy customer requirements [expectations].

The first important step in Quality Management is to identify customer needs or requirements. This can sometimes be a very difficult task ! Once these have been fully identified it is then necessary to provide a formal definition or specification of these written in the language of the organisation.

Suitable processes (activities) need to be determined that will ensure that an organisation actually delivers a product or service that does ultimately meet the specification and in turn the customer needs or requirements. This will require an extensive period of (quality) planning during which the various actions and associated checks that need to be performed will be identified. The planning output will result in a series of instructions, resource requirements and associated responsibilities that when implemented will deliver the required product or service. Once the plans have been communicated and the processes set in motion it will then be necessary to ensure that the plans are followed exactly and continuously. Managerial control will need to be exercised over the processes to ensure that the desired outcomes are achieved.

Quality Management System frameworks have been developed to the extent that they have become in effect the de facto overall management system of an organisation.

Quality Management

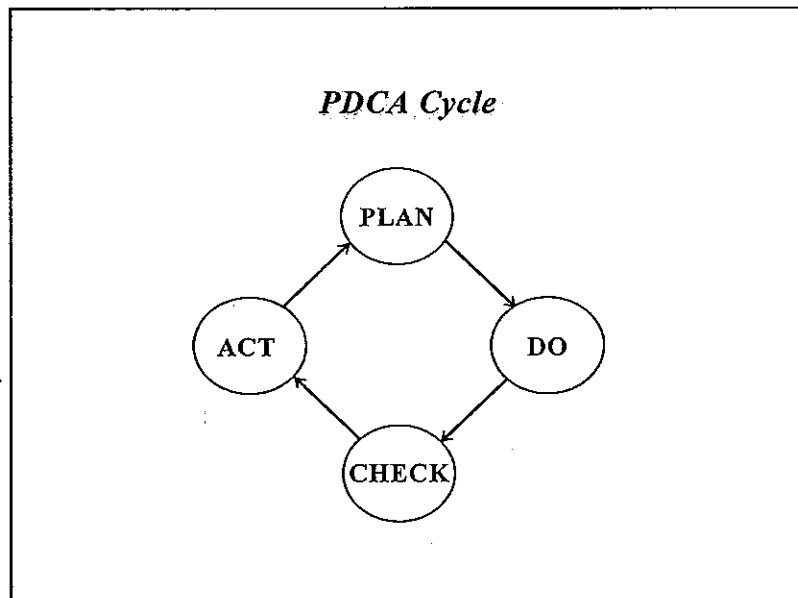
Quality Management is the means by which an organisation ensures that it's products and/or services meet company, customer and regulatory requirements.

It is a combination of resources, responsibilities and actions that together ensure that specified requirements are met.

It is a combination of systematic approaches to doing the work, together with specific checks to ensure that the work has been undertaken correctly.

The "PDCA cycle":

When we become involved with formalised management systems, we are introduced to the concept of formal planning of activities (processes), where the procedures are effectively an output from our planning process. We then do the work in accordance with the procedures (our plan). We need to periodically check to see that we are following our procedures, and if we are not, take the necessary action to rectify the situation, or if the plans were not good enough in the first place, then we need to re-plan. Hence involvement with what is referred to as the "PDCA cycle". Many organisations recognise the importance of re-planning periodically in order to plan to do things better in the future than they have done in the past, and hence they talk in terms of a 'PDCA' spiral of continuous improvement.

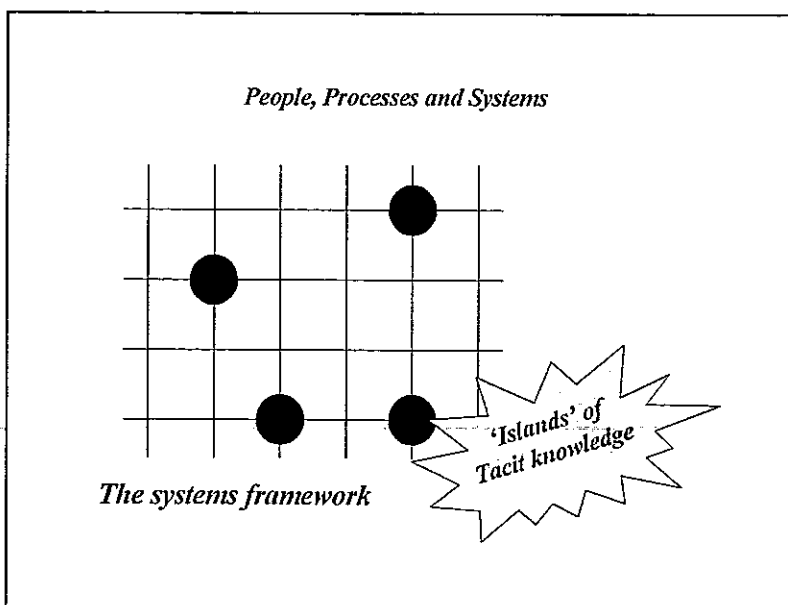


Documenting & Communicating the Management System.

It will be necessary to communicate the methods of working that an organisation wishes its staff to adopt in order to ensure that there is commonality and consistency of approach across the organisation and also to ensure that for certain work activities (processes) it is clear the actions that staff must take in order to ensure that the task is undertaken correctly. This is particularly important where safety related activities are undertaken.

The need for procedures and instructions.

For larger and more complex organisations there will often be a need for more procedures in order to ensure that the organisation functions effectively and in the way desired by management across the totality of the organisation's activities. Management systems are therefore likely to be more comprehensive in larger and more complex organisations, whereas for very small organisations there is often a minimal need for written procedures due to the fact that there may only be the one individual who undertakes a specific task and it would only be this individual who could write the procedure to communicate requirements to themselves! However external organisations, such as a regulatory authority will often need to see written procedures to be able to judge whether a necessary process has been planned effectively. Unfortunately organisations are often required to produce written procedures for no other reason than to provide evidence of control to external parties whereas the organisation itself may have little need of the procedure. (in many situations the procedures may be more appropriate as training documents).



Another consideration when determining the need for written procedures is the competence of the staff undertaking the work activities. Where there are very competent staff there may be less need for procedural detail to support them, and the skill in developing any formal management system is to judge where it is appropriate and necessary to provide written instructional detail, and where it is possible to depend on the competence of individuals. A degree of judgement is necessary in order to provide procedural and reference information that will act in support of the competent staff employed.

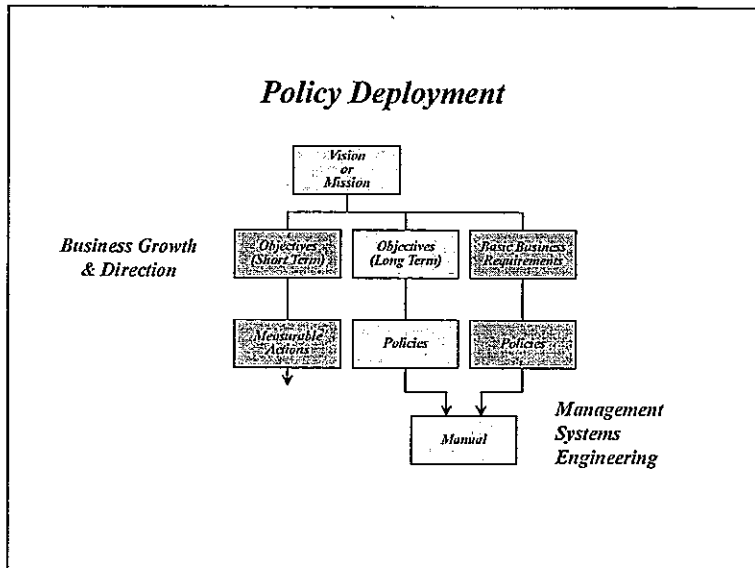
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Documentation hierarchy.

A documented management system is used to 'deploy' an organisation's policies and typically will include:

- Some form of "Vision" or "Mission" statement,
- Statements of organisational wide high level "Policy" together with lower level supporting policies and "objectives",
- A Manual providing an overview of the [Integrated] Management System,
- Documented procedures that the organisation considers necessary to ensure the effectiveness of its operations, (Flight Ops Manual and other SOPs)
- Supporting detailed instructional material,
- Requirements for necessary records.

The Management System Manual should contain and amplify the high level policy, providing lower level supporting policies in relation to key processes together with a brief description of the means of implementation, and reference to supporting procedures. It should be a relatively slim document and provide an overview of the structure of the total documented system. It should be written to help 'drive' the company and not to simply to satisfy the requirements of external parties, however it will inevitably be used to convey key information for the provision of 'assurance' to external organisations, such as customers and / or regulators. Such high level manuals should not contain procedural detail.



Contribution of suppliers.

It is recognised in many regulation that suppliers are important to an organisation. Suppliers are there to provide an organisation with many products and essential support services and an organisation may be very exposed to financial or safety risk as a result of supplier / contractor actions, therefore it is important to select suppliers of key services / products who are capable of supporting an operator in a fully effective and acceptable way and where necessary to assist in the development of their abilities.

Contribution of suppliers.

Supplier management is a key 'quality' discipline involving:

- Supplier selection / evaluation.*
- Communication with suppliers (Contracts and SLAs).*
- Managing the supplier interface.*
- Supplier performance monitoring.*
- Supplier development.*

Our dependence upon key suppliers is too great for the management of them to be left to chance !

Suppliers and / or contractors need to be manage and developed to support an organisation. Supplier management is a major business process involving:

- Supplier selection / evaluation.
- Communication with suppliers (Contracts and SLAs).
- Managing the supplier interface.
- Supplier performance monitoring.
- Supplier development.

Key suppliers need to be selected carefully. It is then necessary to build a good working relationship with them and treat them not as adversaries but as partners with compatible aims and objectives. The relationship with suppliers should be mutually beneficial, and where an operator feels comfortable with a supplier / contractor who lacks resource or competence then it may be to the operators advantage to help to develop their abilities by working more closely with them and where necessary supplementing their resources with its own.

The supplier that provides the lowest quote may be taking short cuts in order to win our business, and unless we are fully aware of their operating costs, of staff, raw materials etc. we should proceed with caution. It is better to pay a realistic economic price for something knowing that the job will be well done rather than pay the lowest price and risk supply failures or defectives that could result in additional costs, or safety risk, to our organisation which together with the initial purchase price could far exceed the price quotation from a well managed and realistically priced supplier.

A formal evaluation can reveal valuable information relating to the strengths and weaknesses of a supplier, and armed with this information we are better able to construct a contract which includes necessary requirements aimed at protecting us against any observed weaknesses (additional control / monitoring activities etc.). The contract should ensure that the responsibilities of both contracting parties are detailed together with suitable performance measures in the form of a Service Level Agreement. *(The evaluation of a supplier / contractor can be considered as a form of Risk Assessment - enabling suitable [mitigation] counter measures to be implemented when the decision to purchase is taken).*

The decision to use a particular supplier will depend upon various factors, however these should include in addition to overall technical competence, the ability to manage fundamental business and product/service related processes, and a willingness to act in support of the contracting party in both the good times and the bad.

The supplier selection process should be formalised to include a systematic evaluation of their overall capability and competence as well as financial soundness. We should be mindful of the need to reduce the overall cost of buying and using a product or service rather than merely the initial purchase price, and hence we need to concern ourselves with the consequences of purchasing decisions.

Once a purchasing decision has been taken we then need to ensure adequate communication.

This is often another activity that is not well managed. There should be defined points of contact between the organisation and the supplier in order to ensure that communication takes place in a controlled and appropriate way with important information being exchanged between both parties using the correct and appropriate channels and important decisions involving the correct staff of both organisations. There is nothing more likely to cause confusion and problems than staff at various levels in both organisations communicating directly and without the knowledge of the main interested parties.

It is normal practice to put in place some form of "Service Level Agreement" with suppliers of key or essential services. Such SLA's need to be clear and concise, and specify service standards in a manner which can be easily measured and thus allow for effective monitoring of supplied services and thus avoid costly (and often acrimonious) disputes.

SLAs and supplier performance monitoring.

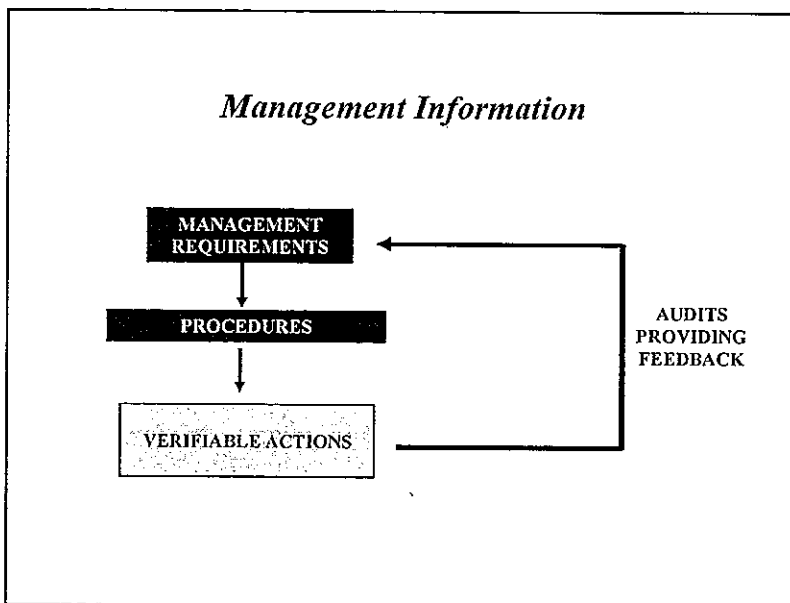
In particular SLAs are very important and need to be constructed carefully to ensure adequacy not only of communication of requirements but also specific levels of achievement against defined objectives.

The contract or SLA should be produced taking into account the results of formal evaluation (identified weaknesses).

Compliance Monitoring.

Compliance Monitoring [Auditing] is not undertaken merely to ensure regulatory compliance, but to search out weaknesses in the management system. The compliance monitoring process is there to serve the needs of management, to provide them with feedback on systems implementation and effectiveness and providing objective data to assist in decision making.

Auditing provides the feedback mechanism which tells us how well our systems are functioning and where improvements could be made.



Auditing is recognised as an extremely powerful technique that may be used by managers alongside other management techniques to ensure adequacy of process implementation and assist in the achievement of objectives, it has become part of the overall process of business management.

Compliance Manager

Although not specifically mentioned by name in Part OPS, many organisations have identified a function to monitor compliance with processes and procedures and general compliance with the regulations. In many cases this has simply been a renamed 'Quality Manager'

The actual regulation states:

Management System.

(c) The operator shall establish a function to monitor compliance of the organisation with the relevant requirements and the adequacy of the procedures. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary.

Personnel requirements.

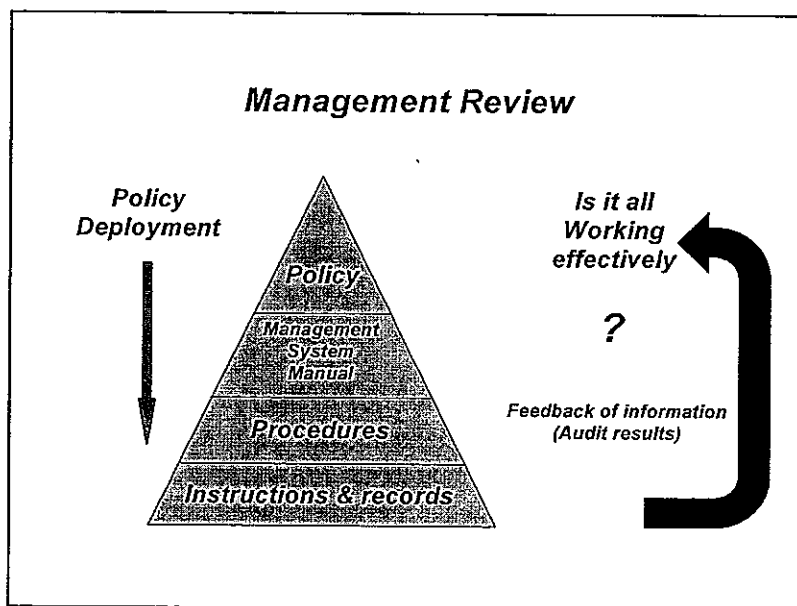
(b) The operator shall nominate:

(2) a person or group of persons with the responsibility of ensuring that the organisation remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the accountable manager.

The implication here is that there needs to be a function that will be responsible for determining the level of compliance monitoring activities that need to be undertaken and for ensuring that the compliance monitoring data is supplied to the Accountable Manager. However the statement under "Personnel requirements" is not quite so logical as it would appear to imply that their needs to be one or more persons with the responsibility for 'ensuring' that the organisation remains in compliance with the regulations, however the only people who can meet this requirement are the nominated Postholders and Process owners themselves !

Management System Review.

Management need to periodically review their Management System to ensure that it is effective and continues to be suitable to fully support the business needs, particularly in the light of changing competitive demands and any new legislation. The effectiveness is indicated by details concerning what has been going wrong in the organisation, such as reports of customer complaints, product / service nonconformities etc., and also from the results of audits. (There is a link here to the Internal auditing activities, where auditing is providing a feedback mechanism to the Accountable Manager on the performance of the management system). The whole purpose of Management review is to ensure the continuing suitability, adequacy and effectiveness of the management system in meeting the organisation's needs, with outputs linking in to the quality policy and objectives. There should also be a strong emphasis on the assessment of opportunities for improvement. The process of management review requires specific inputs to the process and outputs that need to be provided. Audits and process performance are included as important inputs, and improvement actions are the fundamental output. Records from management reviews need to be maintained to demonstrate the effectiveness of the review process.



Auditing

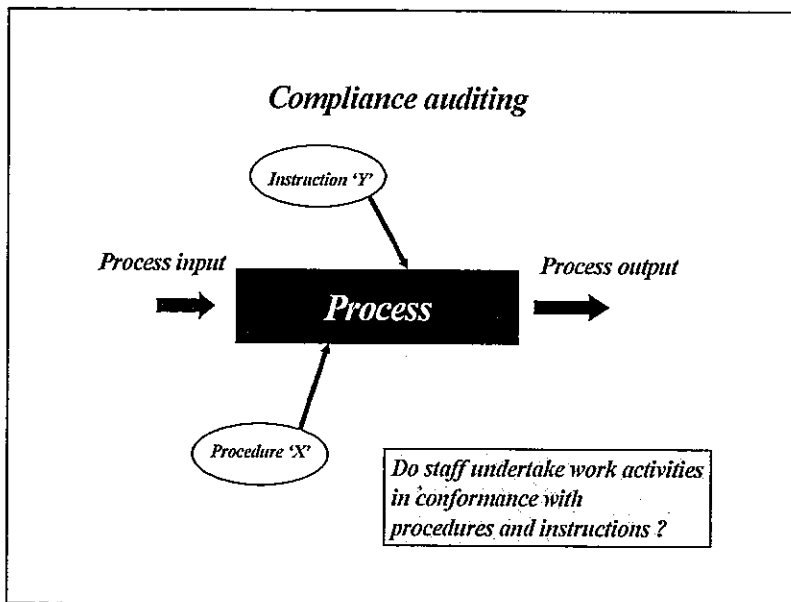
Introduction to Auditing

Audit Process Management

The Audit Process

Introduction to Auditing.

Potentially there are very large numbers of audits that could be undertaken in relation to Flight Crew Licensing, including the activities undertaken by contracted agencies and suppliers. The magnitude of the audit task is often not well understood and the level of resource allocated to auditing often remains inadequate. Over the years there have been improvements with many operators understanding the need to use a multi disciplined team of auditors to undertake audits throughout the broad scope of company operations associated with or in support of flight training activities and resultant licensing of flight crew.

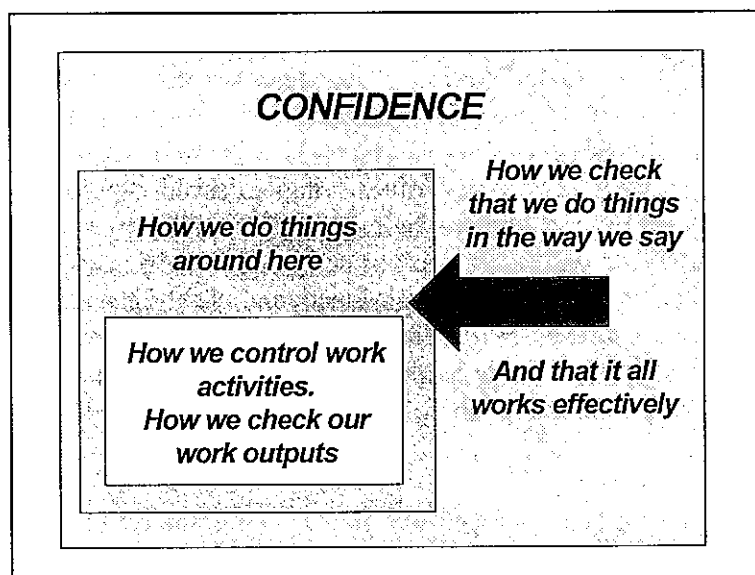


When one examines the detail within Part FCL, the conclusion is that a very significant audit resource is required to verify compliance with each requirement, however by applying the principles of risk based auditing and audit sampling, the audits should be focussed on those aspects of the operation that are considered to have a more significant impact on safety and where there is possibly less confidence or where management feel they need a greater assurance of 'quality'.

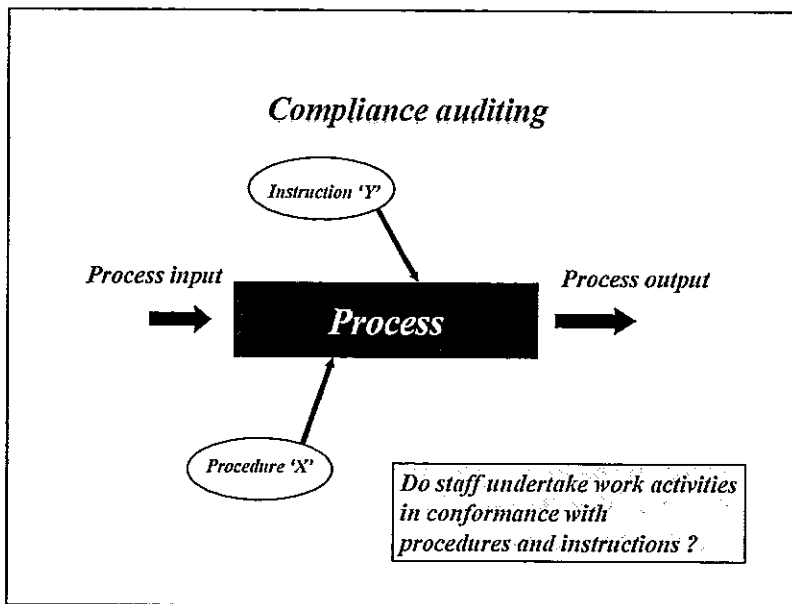
What is an audit ?

Audit is the term used to describe the independent examination of actual practice, or the results achieved, for an activity and the comparison with requirements detailing what should be done, how it should be done, or the results that should have been achieved. Audits are not undertaken to verify that actual practice, or an item, is acceptable in order to allow continuation of the process (delivery of a product, return of aircraft to service, etc.)....

Audits are undertaken in order to provide unbiased and objective data to enable judgements to be made about the overall acceptability of a system, process or products. Auditing is primarily a feedback mechanism for the purpose of providing confidence that a process or system is capable of, and is providing acceptable outputs or outcome. The Accountable Manager requires the "Assurance" or confidence that everything is happening in the way that it is required to happen and that it is all effective.



Auditing is a very powerful tool that may be used by organisations to verify the application and effectiveness of their own management systems or the systems used by their suppliers and contractors. Auditing may also be used in relation to the granting of some form of approval or certification, and as such is regarded by ICAO as a very important and integral part of a regulatory approval and oversight activity. Compliance auditing is undertaken both within an organisation, and also in relation to the selection and use of suppliers and contractors.



Compliance auditing will check to see that procedures and instructions relating to a process are being followed by the involved staff, however a significant weakness in this approach is the acceptance that the process has been well 'engineered' in the first place and that it is a process capable of achieving the desired output consistently and reliably. If the process has not been well engineered then all that will be achieved by the audit is that in the best case scenario a poorly engineered process [that is not capable of achieving the desired outputs consistently and reliably] is being followed to the letter. Clearly it is necessary to not only audit to see that procedures and instructions are being followed, but that the desired outputs are being achieved. This will sometimes necessitate the auditing of process outputs - often termed product audits.

However, the process itself may need to be more frequently monitored in order to provide a more rapid feedback to maintain the process within operating limits, or to provide data enabling a 'picture' of operating performance to be obtained.

Auditor competence.

The competence of those conducting audits is important if an audit 'client' is to have confidence in the results.

Audits should be undertaken by those who have sufficient independence from the activity being audited and who have the necessary competence. Competence exists mainly in various domains. One domain relates to the general skills and practical abilities of an individual to conduct an audit in an objective manner. A second domain relates to the inherent technical knowledge / experience of an individual which will enable them to conduct audits where their knowledge / experience is necessary for them to understand the processes undertaken in the area that they are auditing. A third domain is the necessary familiarity with and understanding of the requirements against which they are auditing. The fourth, and possibly the most important competence, is to be able to conduct the audit without offending others, without acting arrogantly or trying to convey that they are an expert in the work of others!

General Auditor Qualities

Confident
Diplomat
Personable
Inquisitive
Good Listener
Versatile
Constructive
Objective
Resilient
Analytical
Familiar with Management System
Professional

Audit team leaders should also have additional knowledge and skills in team / audit leadership to facilitate efficient and effective conduct of an audit, e.g. audit planning, communication, organising and directing, reaching conclusions, preventing and resolving conflict, and audit reporting.

Auditors and audit team leaders should be periodically evaluated for competence against appropriate criteria relevant to the auditing activities that they are required to undertake.

Auditor Characteristics

*To get along well with other staff
(To be respected)*

Enquiring & logical minds

Prepared to undertake lengthy investigations

To remain Objective and not Subjective or "opinionated"

Major Problems with Auditing

Auditors not given direction by Management

Auditors viewed as a "Police Force"

*Auditors believe that they are an elite group of
"Quality Specialists"*

Management and staff hide facts from the auditors

Internal Auditing.

Auditing undertaken by an organisation on itself is a very powerful and important feedback mechanism which provides both confidence to management and employees that all is going according to plan and also identifies opportunities for improvement. Such audits may be delegated to an external contractor, and may include:

Auditing of Management Systems to verify implementation and effectiveness.

Auditing of projects or programmes of work to verify conformity with Terms of reference, contracts, Quality Plans, etc.

Auditing of industrial processes to verify conformity with process specifications.

Auditing of key business processes and procedures to verify conformity with and adequacy of process descriptions and procedures.

Auditing of key documents, or process outputs to verify adequacy of processes used.

Auditing of product and/or services to verify conformance to product and/or service standards.

For internal compliance monitoring audits, it is often beneficial if a small dedicated team of auditors is not employed, instead a large number of managers and staff being trained as auditors and used in a "cross auditing" capacity. By this means auditors will be auditing other manager's areas of responsibility and will at the same time develop an awareness of other department's problems and difficulties and a far greater understanding of the management systems adopted within their organisation.

Auditing of Suppliers and Contractors.

Auditing undertaken by an organisation upon its suppliers or contractors forms an important and integral part of a supplier management and development programme.

Audits of potential suppliers and contractors to establish confidence in their ability to meet the requirements of the purchasing organisation (can involve system, process and product audits as required), and to assist in the process of supplier selection and determination of supplier control mechanisms.

Audits of existing suppliers to verify conformance with contract requirements.

Audits of existing suppliers as a result of problems experienced and to determine likely causes with a view to requiring targeted corrective action. (May involve system, process and product audits).

Auditing of suppliers and contractors in order to identify opportunities for improvement in the supplier or contractor organisation management system - may be used as an integral part of a "Supplier Development" programme where an organisation wishes to develop the competence of a supplier and so better support the organisation.

Such audits may be delegated to a contracted auditing organisation.

Third Party auditing.

Audits may be undertaken by an independent authority authorised and/or mandated to undertake audits on organisations. Such audits are more frequently of the systems variety, however from time to time process and product audits may also be undertaken if appropriate to the audit objectives.

These authorities can be broken down into:-

Accredited Certification Bodies undertaking audits to verify conformance to a Management System standard for the purpose of granting certification to that standard. Such standards include those relating to Quality, Health & Safety, Environment, Data Security, Business Continuity, Energy Efficiency etc.

Trade organisations specifically set up by members of a particular trade or industry group to undertake audits on behalf of the group, in order to assist purchasing decisions within the group or industry (IATA has put in place both the IOSA and ISAGO audits as safety related auditing processes acting to protect the interests of IATA members and also to raise safety standards throughout IATA member airlines). Thus minimising the audit resource required by individual member companies.

Regulatory authorities operating at an International, National or local level, verifying compliance with International or National law (e.g. in the U.K. HSE - the Health & Safety Executive, etc.).

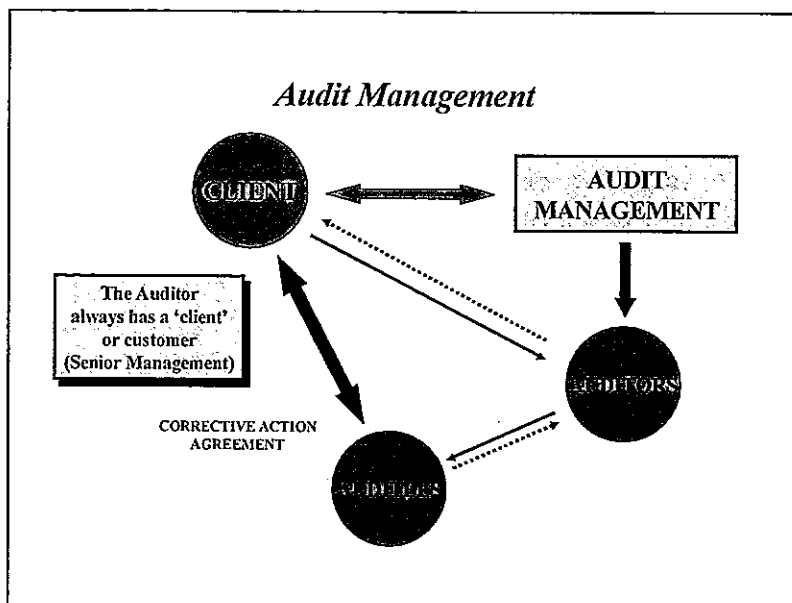
In aviation there are international obligations that require National Aviation Authorities (NAAs) to demonstrate that they operate effective mechanisms for the granting of approvals and the provision of on-going oversight of approved organisations. Such activities rely very much on the use of effective auditing mechanisms, and regulatory authorities therefore are required to demonstrate that they have full control over their audit process and their auditors (inspectors).

Audit Process Management.

Audits should not be undertaken merely to keep auditors employed! Audits should be undertaken when there is a need for information in order to facilitate decision making. However, in many cases, particularly for internal audits, it is the auditors themselves who decide what should be audited and how frequently. This is clearly an inadequate approach, however if management take little or no interest in auditing then it is inevitable that those who appreciate the need, or are enthusiastic about the task will drive the process in the way that they feel best serves the need of the organisation. The end result is an audit system that provides information about aspects of organisational performance that are of little or no concern by senior management, whilst important aspects are left un-investigated.

Management should be in full control of the audit process, participating fully in planning audit programmes, receiving and analysing audit results, and determining the need for, and timescales of, corrective actions. It should not be the task of the auditors to decide what is important to be corrected and how quickly it should be actioned. Unfortunately, in many organisations the auditors assume that they have the responsibility and authority to require (demand) that corrective actions are undertaken in response to audit findings. In these situations auditors are beginning to drive organisations rather than management. If management do not participate in the audit process it will do very little to serve their needs.

We need to fully understand why auditing is necessary, and to set up a mechanism whereby it can be steered by management to serve their needs.



All auditors have a "client", that is an individual or an organisational function that requires information.

Auditors, and the audit process need to be managed on behalf of the client by a function termed "Audit Management".

It is the responsibility of Audit Management to liaise with the client and determine what are the audit needs of the client (what information is required by the client). It is then possible to programme audits to provide this information and arrange for suitable audit resources.

It must be recognised that for certain information auditors with very specialist knowledge and experience may be required.

Once the audits have been undertaken and the information provided to the client, it is then the responsibility of the client to decide if corrective action is necessary and by when. They will either need to liaise directly with the audited functions or request the auditors to undertake this task on their behalf.

By this means management may remain fully in control of the audit mechanism, the auditors merely providing information as required.

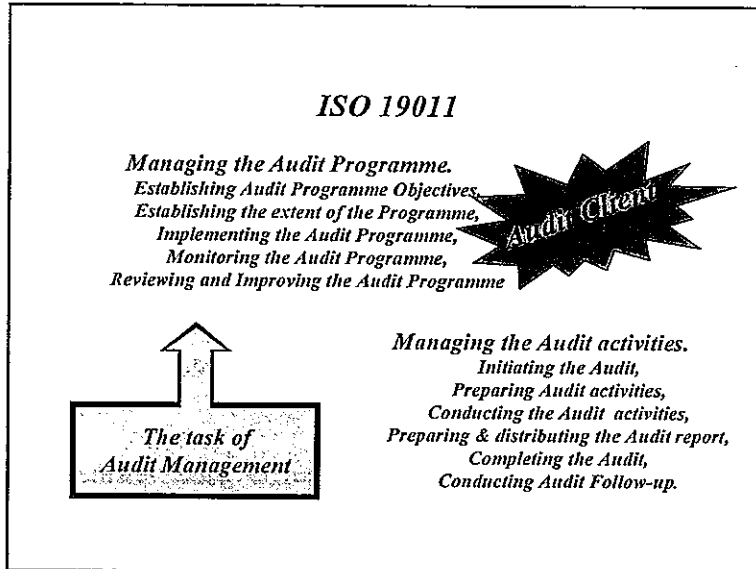
Such an approach is also extremely effective at ensuring important aspects of operation are investigated.

As for the auditors themselves, it is often beneficial if a small dedicated team of auditors is not employed, instead a large number of managers and staff being trained as auditors and used in a "cross auditing" capacity. By this means auditors will be auditing other manager's areas of responsibility and will at the same time develop an awareness of other department's problems and difficulties and a far greater understanding of the management systems adopted within their organisation.

For a regulatory authority the 'inspectors' are undertaking audits on behalf of the function in the authority that makes decisions on approval and the continued operation of an organisation.

Audit programmes.

An audit programme comprises a series of audits undertaken over a specified period of time. Such a programme needs to be effectively managed, and ISO 19011 provides guidance on the management of audit programmes, audit conduct and auditor competency requirements.



ISO 19011 has been prepared in a general way so as to be applicable to different industries and organisations and provides guidance that is intended to be flexible in the way that it is applied dependent upon the size, nature and complexity of the organisation to be audited as well as the objectives and scope of the audit to be conducted. It provides guidance on audit principles, the management of audit programmes, audit conduct and auditor competency requirements. It has been prepared in a general way so as to be applicable to different industries and organisations, is equally applicable to First, Second and Third Party auditing and is now used as the basis for audit approaches throughout the world and by a diverse range of organisations undertaking audits and assessments.

It is important to note that ISO 19011 makes it quite clear that an auditor always has a client, and the sole purpose of undertaking an audit is to provide the 'client' with information. In other words audits are not undertaken to keep auditors employed or for the benefit of the auditors!

It is not necessary for an organisation to have a dedicated team of auditors who's only function is to undertake audits. It is often of great benefit to an organisation if various staff and line managers are involved in undertaking audits, they will develop a better understanding of the requirements which is then transferred back to their own area of responsibility.

It is essential that auditors have a sufficient degree of independence and only undertake audit activities in areas not their direct responsibility, a system of CROSS AUDITING should therefore be devised by Audit Management.

A pool of audit staff should be trained and made available to Audit Management for the purpose of undertaking the audit programme. How many is dependent upon the size of the organisation and how often we wish each member of the audit pool to be involved in audit activity.

Audit Management should develop, in conjunction with Senior Management, a suitable audit programme (usually on an annual basis) and communicate this to all line managers and audit pool members. As soon as possible the individual auditors should be identified for each audit activity. The audit pool should include those with appropriate specialist knowledge to ensure all areas of the organisation are subject to effective audit activity.

THE LEVEL OF AUDIT ACTIVITY SHOULD BE DETERMINED BY THE NATURE AND STATUS OF IMPORTANCE OF COMPANY OPERATIONS AND BY CONFIDENCE IN SYSTEMS IMPLEMENTATION.

This does not however preclude the additional activity of carrying out unscheduled or special audits, which may become necessary due to the occurrence of significant problems in an organisation, a higher level of customer complaints, or instances management require information which the audit tool may be particularly useful in providing.

In such instances the audit schedule should be amended to show the inclusion of additional audits and appropriate notice of intent provided to the auditees. Consideration should also be given to the selection of auditors who may require more specialist knowledge for such audits.

Allocation of audit tasks.

Auditors should be nominated for each individual audit who then have a prime responsibility to ensure successful completion of the audit task, which includes planning, communication with appropriate line management, conduct of the audit, and follow-up as required.

Audit Management should identify not only the part of the organisation (or process) that needs to be audited, but also the specific requirements that need to be verified.

Audit Management should ensure that relative responsibility for audit 'close out' are fully understood, particularly when this does not involve the auditor.

The auditor is responsible for alerting appropriate line management to the impending audit and ensuring adequate communication concerning nature, scope and objectives of the audit together with time required, schedule, and key staff that need to be available. It is sometimes necessary for the auditor to discuss arrangements with line management before they can be finalised.

Line management should be comfortable with all arrangements concerning the audit well in advance, and it is suggested that a formal communication be raised to ensure no misunderstandings.

It must be stated that the degree of formality attached to the above is very dependent upon the size of the organisation and the scale of audit tasks.

The Audit Process.

An audit will not always lead to a formal request for corrective action. Auditing is concerned with the gathering of factual information for the auditor's 'client', and what the client chooses to do with the information is the client's business. Many auditors feel that it is their right to demand corrective action, forgetting that they are there only to serve the needs of the 'client' and the client will decide what is to happen next.

Hence there are two separate sub processes in relation to any auditing activity:

The audit itself - gathering information for the auditor's 'client'

The response to audit findings, including where appropriate both remedial and corrective actions - which is driven by the client and may not even involve the auditor.

Response to audit findings.

It is normal practice to provide a formal written report fully detailing audit findings to the auditee within a reasonable time, and it is often then necessary for the auditee to be required to respond to this report by indicating what action will be taken in response to the audit findings. Such a response may include a "**remedial action**" and also a "**corrective action**".

Remedial Action.

This will detail the immediate "remedial" action that will be undertaken to eliminate the problem that was revealed by the audit. For example to provide the correct issue of a document at a location where an obsolete document was found by the auditor.

Corrective Action.

It will also be necessary for the auditee to investigate why an obsolete document was available for use and to identify what is referred to as the "root cause" (underlying cause) for obsolete documents not being withdrawn and replaced with the correct issue documents. This may require an investigation to determine first if there are many other similar situations and if there are, what is the reason. It may be that the investigation reveals that this is not a frequently occurring problem and hence there is no need for an action to address a root cause.

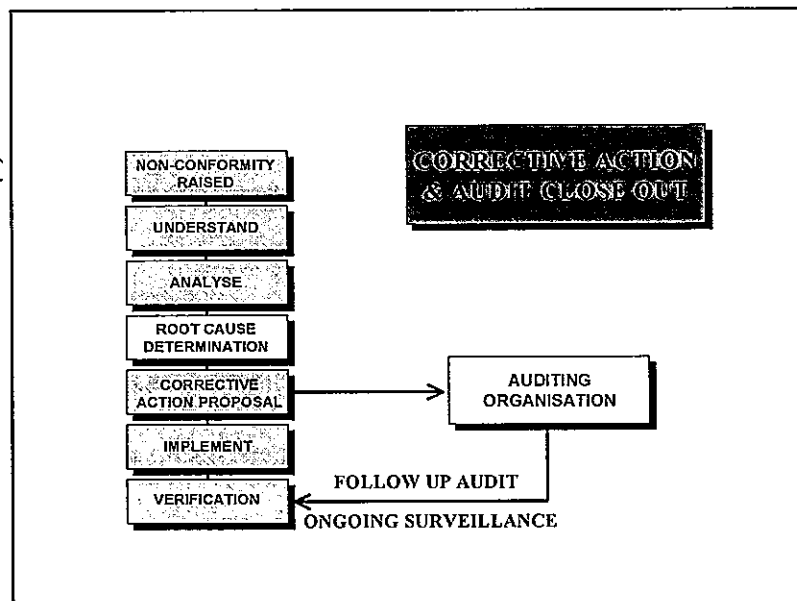
Such an investigation may require the gathering of additional data and analysing as appropriate in order before the root cause of the problem may be determined. This is likely to take time and is the reason why it is not reasonable to request details of corrective actions at the time of the Closing Meeting. The auditee will need to work with reported nonconformities and begin the process of corrective action determination. It will be necessary for the auditee to first understand each nonconformity, and the auditors approach to writing clear and factual nonconformity statements is designed to ensure not only objective audit reporting, but also nonconformity statements that are understandable to the auditees and also to future auditors who may be called upon to undertake audit follow up verification activities.

Auditee management will need to ensure that each nonconformity situation is analysed, where necessary gathering further relevant information initiating detailed investigations, and/or internal audits to provide additional information to enable the root causes of the nonconformity to be determined. It is at this stage that management may wish to employ some of the various problem solving tools and techniques to arrive at suitable fact based conclusions. Once the root cause has been identified it will then be necessary to determine a suitable course of action to address the root cause and so eliminate the possibility of similar nonconformities in the future (audit findings in the form of nonconformities are the symptoms of problems, and by addressing the root cause the symptoms should go away).

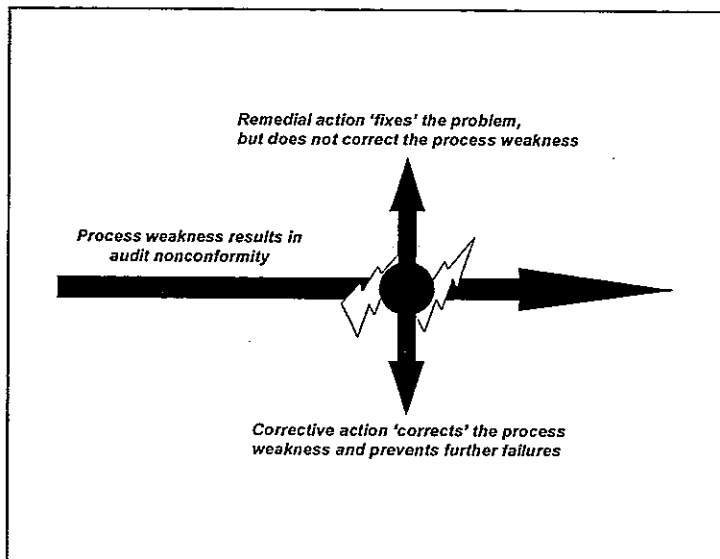
It will be necessary to send the remedial and corrective action proposals to audit management for acceptance / agreement. The original auditor(s) may be called upon to review these proposals and decide whether the proposals are realistic and likely to address the suspected root cause, although it must be remembered that the auditors will not have access to the detailed investigation results and so can only judge from their experience if the proposed corrective action(s) appear to be addressing a likely root cause and also that there is evidence of detailed analysis having been performed and the auditees have not simply resorted to adopting "Quick Fix" measures.

If audit management is satisfied with the proposals (which should also include an appropriate timescale) they should indicate this to the auditees and make arrangements for verification audits to be performed at an appropriate time.

The auditee will then need to implement their proposed remedial and corrective action and undertake their own verification activity to clearly verify that the necessary actions have been undertaken and that the root cause has been satisfactorily addressed and the symptoms first reported as the nonconformity(s) are no longer evident.



Once corrective action has been implemented then audit management should arrange for formal verification that it is effective in overcoming the original non-conformance. This may, or may not, involve the original audit team. A disadvantage of involving non-permanent audit staff (managers, etc.) in this verification activity is that it could become an excessive demand on their time and hence they may 'prefer' not to find so many non-conformances next time!



Audit Management need to be satisfied that the corrective action is taken and effective, this should be formally recorded (preferably on the original audit report form) and the audit 'closed out'. This check on the effectiveness of the corrective action is aimed at establishing that the root cause of the problem has been addressed and that the problem ('symptoms') found on the initial audit is no longer evident. This will require appropriate audit samples to check for the problem previously noted in appropriate areas of the organisation.

It may be useful to check the ongoing effectiveness of any corrective actions again at subsequent audits.

However, it is also important to recognise that in some second party audit situations no formal report may be provided to the auditee, nor may corrective action be requested as there is no intention to use the auditee organisation as a supplier. It may also be fully the responsibility of the purchasing function to determine how this stage of the assessment is to be handled, dependent upon the results and the original objectives of the assessment.

Note: When the regulator [competent authority] raises an audit finding the operator is required to identify the root cause of the non-compliance, produce a corrective action plan and finally demonstrate corrective action implementation to the satisfaction of the regulator [competent authority] within a period agreed with that authority.

Audit Records

The following should be considered for inclusion as part of the formal records of audits undertaken in an organisation:

<p style="text-align: center;">AUDIT RECORDS</p> <p style="text-align: center;">AUDIT IDENTIFICATION</p> <p style="text-align: center;">AUDITOR DETAILS</p> <p style="text-align: center;">PLANNING DATA</p> <p style="text-align: center;">CHECKLISTS</p> <p style="text-align: center;">AUDITOR NOTES</p> <p style="text-align: center;">NON-CONFORMANCES</p> <p style="text-align: center;">AUDIT REPORT</p> <p style="text-align: center;">CORRECTIVE ACTION PROPOSALS</p> <p style="text-align: center;">CORRECTIVE ACTION VERIFICATION</p>
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Remember, records are evidence of effective operation of the management system. We need to demonstrate that audits are effectively planned, undertaken and closed out.

Auditee management should determine what is to be retained as audit records.

How to Plan, Conduct and Report Audits

Preliminary Preparation

Detailed Planning

Audit Entry

Audit Conduct

Searching for Evidence

Conducting Interviews and Asking Questions

The Psychology of Auditing

Auditor and Auditee Tactics

Recording the Results

Evaluating the Findings

Audit Exit

Formal Reports

Preliminary Preparation.

The process that will be detailed in this section is applicable to the planning and conduct of internal audits or audits of a supplier or contractor. There will be a management function responsible for allocating an audit task to an auditor. For internal audits this is likely to be an Audit Manager or Compliance Manager. If the audit is being conducted by an audit team then it is likely to be the team leader who will allocate the audit tasks to the individual team members. Once an auditor has been requested to undertake an audit task some preliminary preparation will be necessary.

The audit objectives and scope together with the audit 'sample' should be identified by audit management. The sample will be in the form of specified regulatory or management system requirements, or specific company Exposition or Manual requirements. (only in certain circumstances would an auditor select the sample themselves, e.g. audits of suppliers where the purchasing function might leave this to the auditor).

It is a fundamental principle of auditing that the sample of requirements to be verified should be relevant to the area being audited and should be limited in number to ensure that the auditor can satisfactorily undertake the verification within a reasonable timeframe.

Once the audit task has been allocated, the auditor must obtain information as necessary to develop an understanding of the audit target area. This is best done by gathering documentation and studying as appropriate and even by having preliminary discussions with the appropriate auditee management and in some cases those with a technical knowledge applicable to the target area. (In some cases it may be beneficial to include technical experts in the audit team). Thus the auditor develops an understanding of WHO, WHAT and HOW relative to the target area as well as physical layout, staff numbers, technologies involved, etc., etc. Techniques such as Process Analysis/Process Modelling may be used to assist with this task.

THIS UNDERSTANDING IS VITAL

It is also necessary to communicate with auditee management what is to happen, when, by whom, and what part the auditees must play in the process. The full scope of the audit must also be agreed and again a preliminary meeting between auditor(s) and auditee management will assist the communication process.

Detailed Planning.

Once the preliminary preparation has been completed and the auditor has a good understanding of the audit task ahead of him/her it is then necessary to undertake detailed audit planning activities. The methodology that will be adopted is as follows:

STEP 1: Be fully aware of the particular requirements to be verified.

STEP 2: Understand how the requirements apply in the area(s) to be audited.

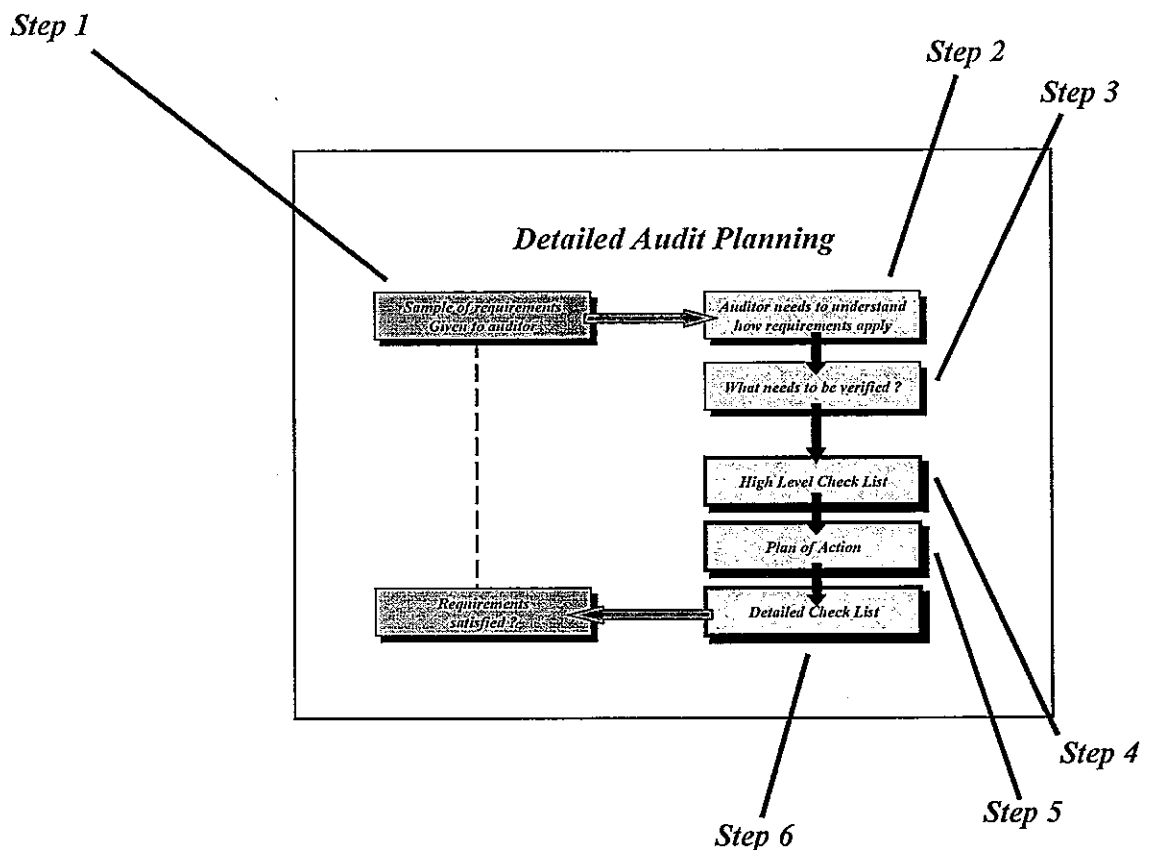
STEP 3: Identify exactly what the auditor must verify.

STEP 4: Develop the 'High Level' check list.

STEP 5: Determine a 'Plan of Action'.

STEP 6: Develop a 'Low Level' check list.

These will be looked at in turn and using a simplified company activity to demonstrate how the methodology is applied.



A simple example:

As an example, consider a typical Approved Training Organisation (ATO) that conducts a variety of simulator type rating training courses for a number of client airline operators. The ATO also conducts skill tests, proficiency checks and assessments of competence for pilots undertaking the suite of courses available. The results of these checks and tests are usually good, reflecting the ATO's high training standards, however, from time to time, and similarly to other ATO's, some students partially pass or fail the tests. *An internal auditor has been requested to undertake an audit of the processes relating to the conduct of skills tests and proficiency checks, specifically, the post-test/check procedures by instructors and examiners.* The auditor, however, has very little knowledge of this particular part of the organisation and so must first develop an understanding that will be sufficient to enable a meaningful audit to be undertaken. The auditor has also been requested to restrict the audit sample to (*Part FCL.1030 Conduct of skill tests, proficiency checks and assessments of competence*), together with the corresponding company requirements as detailed in an Exposition or Management Systems Manual and any associated procedures.

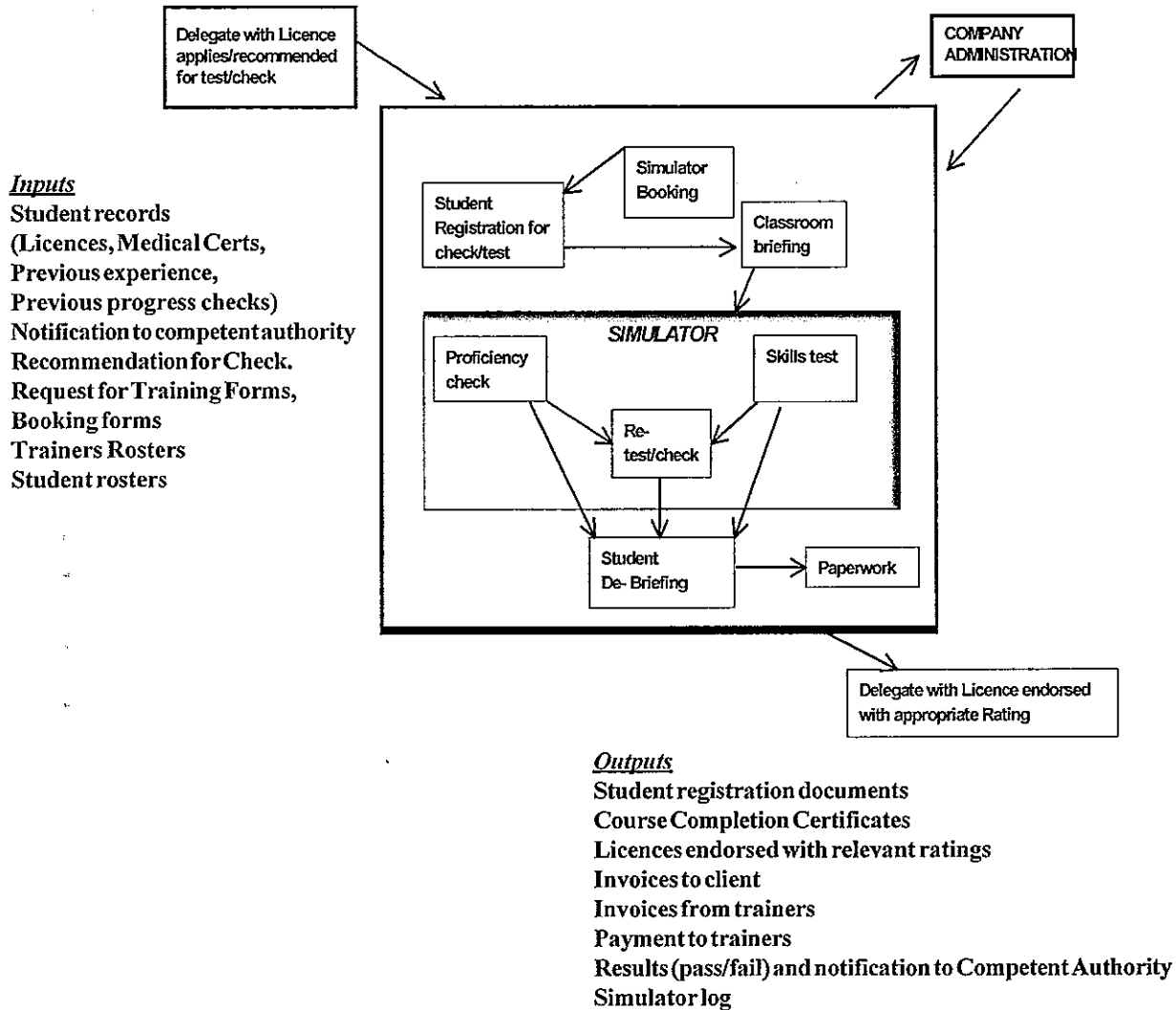
<i>Audit task:</i>	<i>Verify compliance with the EASA Part FCL.1030 requirement, Training Manual and associated procedural requirements in the ATO's execution of procedures post -proficiency checks and skill tests.</i>
<i>Scope:</i>	<i>Simulator Training Facility,</i>
<i>Audit sample:</i>	<i>Part FCL. 1030 Requirement Conduct of skill tests, proficiency checks and assessments of competence.</i>

For the area(s) of the company that are to be the subject of audit activity the auditor must first develop a good understanding of what activities are undertaken, how and in what order. This may be assisted by analysing the processes undertaken. Once this has been done it is then a relatively straightforward task to identify which of the management criteria have some scope for application in relation to the different activities. For any area of a company we may represent it thus:



We may now list all of the inputs, activities undertaken, and outputs. This will help us to develop a good understanding of what is involved in this particular area of the company. It may then be helpful to draw the process steps undertaken within that area of the company (even if some guesswork is involved!).

PROCESS ANALYSIS
(Proficiency Checks / Skills Tests)



ACTIVITIES

- Qualified student applies or is recommended for test/check
- Simulator time booked
- Student registers for check/test
- Student briefed by SFI/SFE
- Test/Check undertaken in Simulator
- Student debriefed with results
- Pass, partial pass or fail – re-test if appropriate.
- Relevant documentation to company administration/Competent Authority
- Students Licence signed or endorsed as required.

STEP 1: Be fully aware of the particular requirements to be verified.

For this example the auditor has only been requested to verify one of the Part FCL.1030 requirements – Conduct of Skills Tests, proficiency Checks and assessments of competence. *(It is sometimes the case that the person or organisation requesting the audit has little understanding of audit sampling and so may need to rely on the auditor to select an appropriate sample dependent upon the objectives of the audit).*

STEP 2: Understand how the requirements apply in the area(s) to be audited.

In relation to the selected requirement and the activities that are to be the focus of audit attention the auditor must now decide how the requirements apply, and whether in part or in full. After having undertaken a process analysis, and/or spoken to staff within the target area the auditor should now read carefully the selected requirements of Part FCL.1030 and the associated manual and procedural requirements and clearly understand how the requirement applies to the activities undertaken within the audit target area.

STEP 3: Identify exactly what the auditor must verify.

The auditor must now decide what it is that is to be verified in relation to the identified requirement.

ARE THE POST TEST/CHECK PROCEDURES (performed by the ATO's Examiners - on behalf of the Competent Authority) CARRIED OUT IN ACCORDANCE WITH THE APPROPRIATE REQUIREMENTS OF PART FCL.1030 ?

However, this statement is somewhat unspecific and it must be translated into more specific requirements relating to Part FCL.1030. The determination of more specific requirements will result in an auditor's High Level Check List. It is now necessary for the auditor to examine closely the requirement in order to determine exactly which elements of that requirement are applicable to the activities undertaken by instructors and examiners post-test or check. Process Analysis and a good understanding of an organisation will make this decision making easier. Once this check list has been developed it will then be necessary to use the organisation's Training Manual and associated procedures to develop the final check list, which we shall refer to as the "High Level" check list".

The auditor must examine the PART FCL.1030 Regulation and decide which parts of it are relevant to the audit task. The following is an extract from PART FCL.1030 and the auditor has identified (in bold text) the component parts or elements of it that are applicable to the Audit Task.

Extract from PART FCL.1030

Bold text indicates the components of the regulation that are relevant for the audit task.

FCL.1030 Conduct of skill tests, proficiency checks and assessments of competence

(a) When conducting skill tests, proficiency checks and assessments of competence, examiners shall:

- (1) ensure that communication with the applicant can be established without language barriers;
- (2) verify that the applicant complies with all the qualification, training and experience requirements in this Part for the issue, revalidation or renewal of the licence, rating or certificate for which the skill test, proficiency check or assessment of competence is taken;
- (3) make the applicant aware of the consequences of providing incomplete, inaccurate or false information related to their training and flight experience.

(b) After completion of the skill test or proficiency check, the examiner shall:

- (1) inform the applicant of the result of the test. In the event of a partial pass or fail, the examiner shall inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained. The examiner shall detail any further training requirement and explain the applicant's right of appeal;
- (2) in the event of a pass in a proficiency check or assessment of competence for revalidation or renewal, endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence;
- (3) provide the applicant with a signed report of the skill test or proficiency check and submit without delay copies of the report to the competent authority responsible for the applicant's licence, and to the competent authority that issued the examiner certificate. The report shall include:
 - (i) a declaration that the examiner has received information from the applicant regarding his/her experience and instruction, and found that experience and instruction complying with the applicable requirements in this Part;
 - (ii) confirmation that all the required manoeuvres and exercises have been completed, as well as information on the verbal theoretical knowledge examination, when applicable. If an item has been failed, the examiner shall record the reasons for this assessment;
 - (iii) the result of the test, check or assessment of competence.

(c) Examiners shall maintain records for 5 years with details of all skill tests, proficiency checks and assessments of competence performed and their results.

(d) Upon request by the competent authority responsible for the examiner certificate, or the competent authority responsible for the applicant's licence, examiners shall submit all records and reports, and any other information, as required for oversight activities.

STEP 4: Develop the 'High Level' Check List.

The relatively unspecific may now be developed into more specific questions that **MUST BE ANSWERED BY THE AUDITOR**. Hence we develop the auditor's **HIGH LEVEL** check list drawing from the requirements that *must* be met by the examiner in this instance. With reference to the PART FCL.1030 requirement:

“After completion of the skill test or proficiency check, the examiner shall:

(1) inform the applicant of the result of the test. In the event of a partial pass or fail, the examiner shall inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained. The examiner shall detail any further training requirement and explain the applicant's right of appeal;

(2) in the event of a pass in a proficiency check or assessment of competence for revalidation or renewal, endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence;”

These may be turned into High Level Check List questions as follows:

(1) Does the examiner inform the applicant of the result of the test? In the event of a partial pass or fail, does the examiner inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained?

Does the examiner detail any further training requirement and explain the applicant's right of appeal?

(2) In the event of a pass in a proficiency check or assessment of competence for revalidation or renewal,

does the examiner endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence?

.....and so on until all the applicable parts of the requirements have been addressed.

Clearly the answers to those questions will be YES or NO. If the auditor is provided with sufficient information to be able to answer YES to each question then the ATO's Examiner, in this instance, has met the relevant requirements of PART FCL.1030.

An internal auditor would need to develop a High Level Check List working initially from the highest level requirement such as a regulatory requirement that the organisation has to meet, and then add to this check list by examining the information contained within its Manual and associated procedures setting out the organisations intentions with respect to the high level requirements. This will now be illustrated using extracts from a typical Manual and associated procedure.

EXAMINERS

Policy:

It is a company policy that all examiners, while having been appointed by and at all times acting on behalf of the XYZ CAA will conduct examinations, tests and checks in accordance with the relevant requirements of PART FCL, This Training Manual and any associated procedures referred to in this manual, in fair and equitable manner.

Implementation:

Examiners will at all times ensure that they are qualified for examination purposes in accordance with the requirements of Part FCL, and likewise that each applicant is appropriately qualified to undertake such a test or check.

Examinations and tests will be carried out in the company training department, using the company training rooms for both the briefing and debriefing of applicants prior to and after completion of tests and checks.

Adequate communication will be established with the applicant prior to the commencement of each check or test. If the examiner believes if there is inadequate communication for whatever reason, between himself/herself and the applicant, the check or test must not be performed until the issue has been resolved.

Examiners will ensure that the correct test or check format, as specified by the relevant requirements in Part FCL is employed at all times during a test or check.

Examiners will, upon completion of a test or check, and without undue delay, inform the applicant of the result of same, the reasons for the result, and, if applicable, any further training requirements in addition to the applicants' right of appeal.

Examiners will complete all relevant documentation immediately after the test or check, and personally ensure that it is sent to the competent authority without undue delay, via the company's mail outbox, located in the company administration office. The Examiner will at the same time sign the company mail outbox log, indicating that the documentation has been posted.

Procedures:

Communication before, during and after checks and tests. EXP0017
Examiners administration guide. EXP0021
Procedures in the event of a Partial Pass or Fail. EXP0027

What the auditor has selected from the manual.

High Level Check list development.

REQUIREMENT
(Part FCL.1030 Requirement)

After completion of the skill test or proficiency check, the examiner shall:

(1) inform the applicant of the result of the test. In the event of a partial pass or fail, the examiner shall inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained. The examiner shall detail any further training requirement and explain the applicant's right of appeal;

(2) in the event of a pass in a proficiency check or assessment of competence for revalidation or renewal, endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence;

INTENT
(Manual Requirements)

Examiners will complete all relevant documentation immediately after the test or check, and personally ensure that it is sent to the competent authority without undue delay, via the company's mail outbox, located in the company administration office.

The Examiner will at the same time sign the company mail outbox log, indicating that the documentation has been posted.

CHECKLIST
(What the Auditor must find out)

Does the examiner inform the applicant of the result of the test?

In the event of a partial pass or fail, does the examiner inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained?

Does the examiner detail any further training requirement and explain the applicant's right of appeal?

In the event of a pass in a proficiency check or assessment of competence for revalidation or renewal,

does the examiner endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence?

Do Examiners complete all relevant documentation immediately after the test or check, and personally ensure that it is sent to the competent authority without undue delay, via the company's mail outbox, located in the company administration office?

Does the Examiner at the same time sign the company mail outbox log, indicating that the documentation has been posted.

The auditor may now refer to the appropriate associated procedure(s) and extract relevant requirements that are then incorporated into the High Level Check List. Thus, examining the procedure associated with the previous Manual extract:

Extract from EXP0027 - Procedures in the event of a Partial Pass or Fail.

In the event of a candidate achieving only a partial pass, or indeed failing the test or check, the examiner must inform the candidate of the result without undue delay in the post simulator de-brief, and also the exact reasons for same.

It is recognised by the ATO that a candidate who partially passes or fails a test or check may have demonstrated competence in many of the disciplines examined, regardless of the overall result, and the examiner must highlight this to the candidate to encourage confidence going into a re-test scenario.

The examiner must stress that the privileges of the candidates rating may not be exercised in any way until a full pass has been obtained.

The examiner must specifically outline any further training that will be necessary (if applicable) before a re-test may be taken by the candidate. The projected time span, if available, for such training must also be outlined by the examiner to aid the candidate with planning for such a test.

The right of appeal (of the candidate) must be discussed in the post simulator de-brief, and examiners must openly ensure that the candidate is fully aware of this entitlement and, should the candidate choose to appeal the decision, that it in no way negatively effects the rapport between the candidate and the ATO, or the candidate and the examiner.

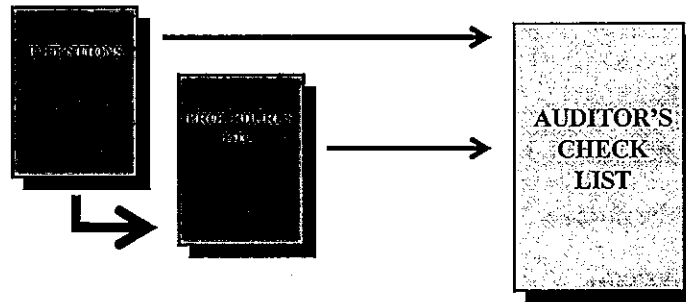
The examiner must take time to answer any reasonable questions from the candidates after the debrief.

If the examiner cannot answer a specific question, he must bring it to the attention of the A's Training Director, and if necessary, to the Competent Authority.

What the auditor has selected from the procedure.

The above italic and bold text indicates those requirements that have been selected by the auditor for this particular audit. (Another auditor may, in the future, select different requirements from the same procedure).

High Level Check List Development



Does the examiner inform the applicant of the result of the test?

In the event of a partial pass or fail, does the examiner inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained?

Does the examiner detail any further training requirement and explain the applicant's right of appeal?

In the event of a pass in a proficiency check or assessment of competence for revalidation or renewal, does the examiner endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence?

Do Examiners complete all relevant documentation immediately after the test or check, and personally ensure that it is sent to the competent authority without undue delay, via the company's mail outbox, located in the company administration office?

Does the Examiner at the same time sign the company mail outbox log, indicating that the documentation has been posted.



Does the examiner inform the applicant of the result of the test?

In the event of a partial pass or fail, does the examiner inform the applicant that he/she may not exercise the privileges of the rating until a full pass has been obtained?

Does the examiner detail any further training requirement and explain the applicant's right of appeal?

In the event of a pass in a proficiency check or assessment of competence for revalidation or renewal, does the examiner endorse the applicant's licence or certificate with the new expiry date of the rating or certificate, if specifically authorised for that purpose by the competent authority responsible for the applicant's licence?

Do Examiners complete all relevant documentation immediately after the test or check, and personally ensure that it is sent to the competent authority without undue delay, via the company's mail outbox, located in the company administration office?

Does the Examiner at the same time sign the company mail outbox log, indicating that the documentation has been posted ?

Does the examiner specifically outline any further training that will be necessary (if applicable) before a re-test may be taken by the candidate?

Does the examiner outline the projected time span, if available, for such training must to aid the candidate with planning for such a test?

STEP 5 : Decide Plan of Action

The auditor must now plan how to obtain information and evidence to be able to answer high High Level questions.

Where to start.

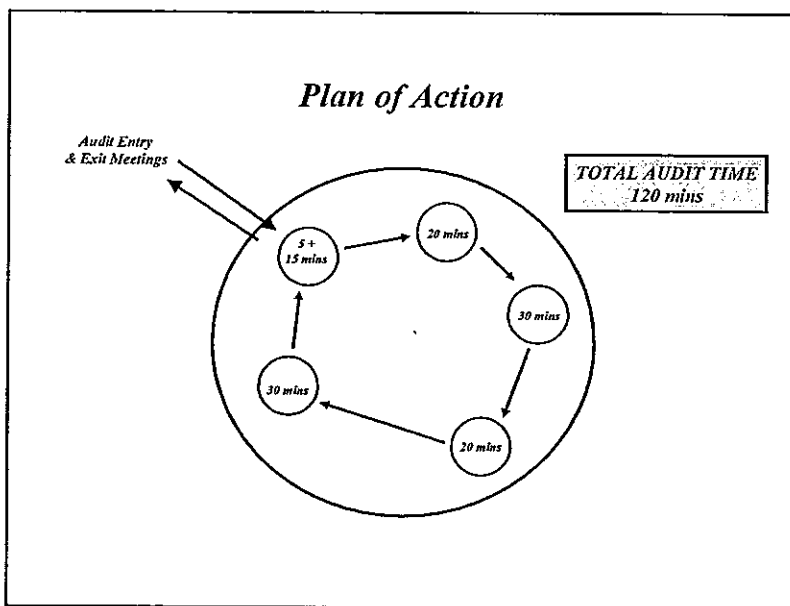
Who to talk to first.

Where to go next and who to talk to next.

Where to observe the process?

Where to test the system?

THUS A PLAN OF ACTION IS DEVELOPED (See also Audit Methods)



For the above example it might be necessary to adopt the following plan and allocate time as follows:

Head of Training	5 mins.
Company Administration Office	20 mins.
Observation of Examiner briefing/de-briefing candidate	30 mins.
Skills Test or Proficiency Check candidate	20 mins.
Examiner	30 mins.
Head of Training	15 mins.

Clearly it is necessary for the auditor to have an understanding of how the company is organised and who the key staff are in relation to the activity being audited. The Plan of Action is very necessary to ensure effective use of the limited time that is available to the auditor, and also to ensure that information is gained in a logical and systematic manner that causes the least disruption to the auditees. It should also be remembered that it is normal practice to start and end an audit of an area of an organisation with the most senior person, out of common courtesy and also because they are likely to want to know if anything important has been found by the auditor in their area of responsibility!

Thus for our example, some ow Level check list questions might be:

Head of Training:

Could you please explain how delegates are deemed suitable to commence skills tests or proficiency checks?

Company Administration Office Staff:

How do you ensure that the required paperwork is sent to the Competent Authority on completion of each proficiency check?

If the examiner forgets to lodge the paperwork with you, what methods have you of reminding him of this fact?

The Examiner:

How do you decide on any further training required by a candidate in the event they receive a partial pass or a fail in a proficiency check or skills test?

By what method is this outlined to the candidate?

Etc., etc.

Questions should enable the auditor to answer the High Level Check List questions. However it is important to recognise at this stage that the auditor would also need to gain factual evidence that actual practice was fully in accordance with any statements made, and thus the need to gain tangible or "Objective" evidence of conformity with written or stated detail.

THE AUDITOR MUST ALWAYS SEEK TO
VERIFY ANSWERS GIVEN BY
OBSERVATION OF ACTUAL PRACTICE

"OBJECTIVE EVIDENCE".

The "Low Level" check list is in practice a series of reminders to the auditor about the questions that need to be asked, things to be examined (documents, products, materials etc.), and records of previous actions and results that need to be reviewed, in order to obtain the necessary objective evidence to enable the auditor to answer the High Level Check List questions. The "Low Level" check list will also detail the sample sizes that the auditor intends to take (the actual quantity of documents, etc. to be examined).

LOW LEVEL (DETAIL) CHECK LIST
QUESTIONS TO BE ASKED TOGETHER WITH
AUDIT SAMPLE

For our example the "Detail Check List" might also include, in addition to the previous questions, the following reminders:

DOCUMENTS TO BE EXAMINED

Candidate test/check results

(to check if the relevant forms have been completed by the examiners)

**Examiner reports on candidates who failed or partially
passed checks or tests.**

Re-test/check schedules, and outlines of further training requirements
*(to check if the examiners are adhering to the company procedures laid
down in the event of candidates not passing checks/tests)*

RECORDS TO BE EXAMINED

Candidate's training files

*(to see if the candidates are suitably qualified before being permitted to
take the tests/checks)*

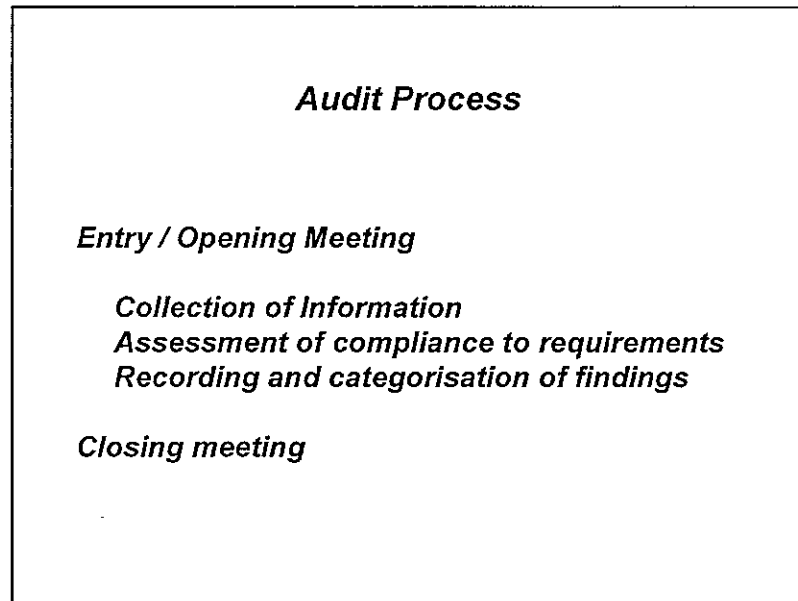
ACTIVITIES TO BE OBSERVED

Debriefing of candidates by examiners

*(to verify that examiners are correctly debriefing candidates after a test/
check and completing the relevant paperwork without due delay).*

Audit Entry

The basic process adopted for any audit follows a fairly standard sequence of events which can be summarised as follows:



Before undertaking an audit in any area of an organisation it is important to ensure that the manager or supervisor of the area is fully aware of what is about to take place, who is involved and how results will be communicated. It is not possible to overcommunicate where auditing is concerned, memos are invariably misread, not understood, or filed for later attention, and in addition to holding a short Entry meeting it is advisable to verbally communicate audit intentions a couple of days in advance of the audit to check that the the auditor(s) is expected and the reason for audit understood.

Auditee management should be informed of audit times and durations, audit objectives and scope, auditors involved, key auditee staff required to be present and any other special requirements the auditors may have (guides, access to relevant documents such as contracts etc., access to controlled environments, etc. etc.).


Finally upon commencement of the audit itself the audit team should arrive on time and re-communicate all previously communicated details at a short Audit Entry meeting. The Audit Entry meeting should be conducted by the auditor with auditee management (senior management of area being audited) together with other relevant key staff as determined by senior management or suggested by the team leader.

The degree of formality adopted for Audit Entry meetings is largely determined by the type and magnitude of the audit task, size of organisation and relationships between auditors and auditees. For internal audits Entry and Exit meetings are relatively informal affairs, however the degree of formality will need to be adjusted to suit the situation. For example if the auditor is auditing in an area of the company where none of the managers has been met before then the level of formality will need to rise.

Clearly if the audit was undertaken by a team of auditors it will be the responsibility of the team leader to arrange for, and conduct the Entry and Exit meetings.

A typical agenda for such a meeting, which should last no longer than fifteen minutes, is as follows:

Opening Meeting



- *Introduces the audit team to the auditee's representatives*
- *Reviews the audit plan, scope and objectives for the audit*
- *Establishes the official communication link between department representatives and audit team*

For relatively small audits, Audit Entry meetings will be a short 'get together' between an auditor and an appropriate line manager or supervisor which may even form part of the audit itself.

Audit Conduct

This should be conducted in accordance with the auditor's Plan of Action, keeping to the set times as far as possible. Remember that the purpose now is to get on with the job and obtain the necessary objective evidence to be able to answer ALL of the questions on the High Level Check List.

As non-conformances are found they should be clearly recorded in a formal manner and agreement sought that the facts leading to the non-conformance are true and accurate.

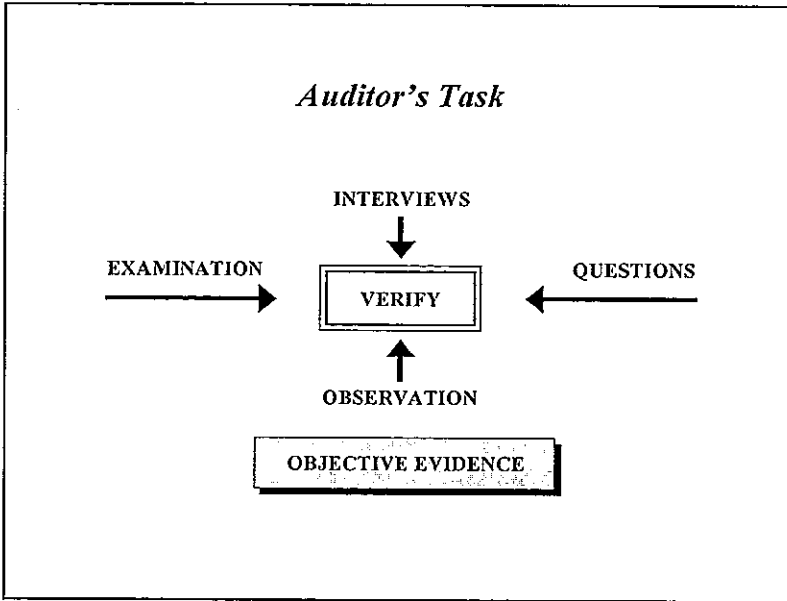
As the audit progresses we may find that trails require to be followed which could detract from the individual auditor's plan, or even major concerns that need to be followed up and so result in a major change to the original audit plan. How should these situations be handled and controlled? It is a prime responsibility of the auditor to ensure that the audit is satisfactorily completed, having covered all areas originally decided upon and checked all appropriate system requirements. Audit trails that are relevant to the audit objectives should be followed and the Plan of Action amended accordingly. Audit trails that do not relate to the audit objectives should be followed if they relate to significant safety aspects, otherwise they should be noted and saved for later in the audit (if there is time) or simply recorded and reported back to Audit Management as possible concerns that have not been verified.

It is not normal practice for internal audits to request staff to accompany individual auditors in the role of 'guides', however when auditing in organisations external to one's own then this is a protocol that should always be adopted. The role of 'guides', is to show the auditors where to go and to introduce them to interviewees and, most importantly to act as witness to facts found that relate to non-conformities. It is most important that the true role of such guides is fully understood by both the auditors, the auditees and the guides themselves. Guides are not there to act as a buffer between the auditors and the auditees, they should not themselves be audited, nor should they cut across the auditor or auditee by asking or responding to audit questions. They are there to ensure that the auditors are able to move around freely in the company, are accompanied at all times to meet with company confidentiality and Health & safety requirements, and to ensure that fair play prevails. In this latter respect, it is sometimes the case that either the auditor or the auditee misunderstands what is being said and in this case the guide can be valuable to see that such misunderstandings do not occur. The guide must also sometimes act in the capacity of Interpreter, not only from the foreign language aspect, but also to interpret company or technical terminology for the auditors.

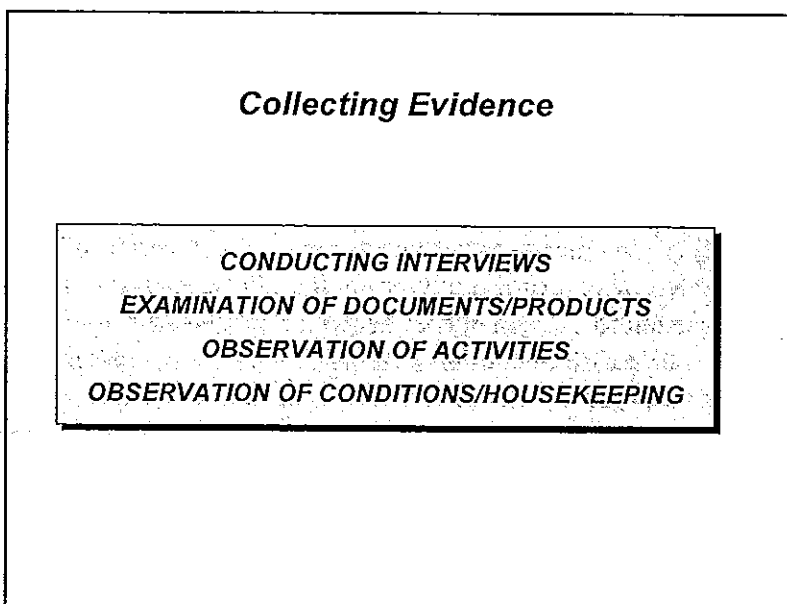
As the guides can have such a significant and important role it is well to select them with care and choose suitable staff for this function. Inevitably a company will choose guides from its own audit staff.

Searching for Evidence.

Audits involve the collection of evidence in order to verify that what should be happening is actually happening. That practice is in line with intent.

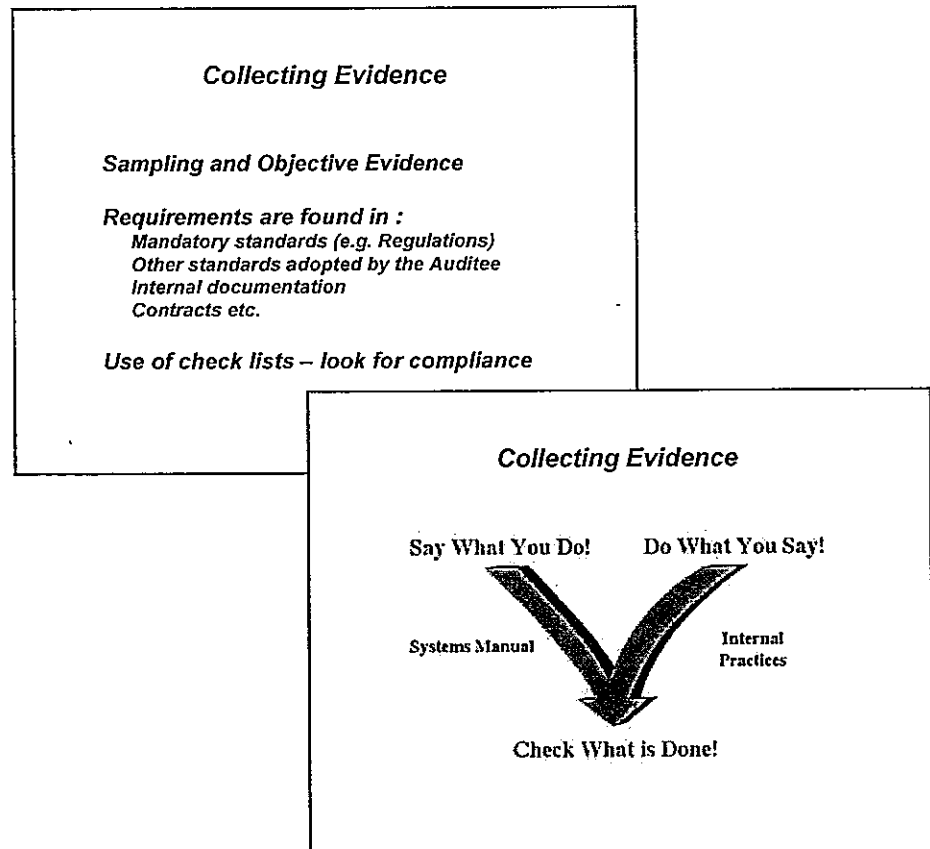


Guidance contained in ISO 19011 suggests that evidence should be collected through interviews, examination of documents and observation of activities and conditions in the areas of concern.



The auditor's Low Level checklists and associated plans of action will generally steer the audit process through a range of activities aimed at searching out evidence to confirm conformance with the High Level checklist. The task of the auditor is to verify that what is prescribed in the documented management system is happening in practice, what is stated by management to be happening is happening. Information gained through interviews should be tested by obtaining the same information from other interviews or independent sources such as observation of practice, materials/products and records.

The auditor always needs "**Objective Evidence**", however we must also take the view that the auditees are innocent until proven guilty, so we are searching for objective evidence of nonconformity to stated requirements.



Throughout the audit a certain degree of flexibility needs to be maintained. We must adhere as much as possible to our audit plan and remain true to our audit sample as detailed in our checklist. However we must not become a slave to the checklist.

At the time of audit we may use a combination of audit strategies and techniques in order to test the system and verify conformance to requirements. The auditor should also maintain a degree of flexibility and be prepared to follow audit trails as they arise.

Approaches to auditing.

The auditor may decide to start with managers and work down through the structure to working level, or start at working level (possibly by observation) and then work up through the structure to supervisors and managers.

The auditor follows a logical sequence of process steps either starting at the input to the series and progressing to the output or working from the output and progressing back to the input.

During the course of an audit the auditor uncovers something that is worthy of further investigation, however this now leads away from the original plan of action and may even involve progressing the audit into other areas of the organisation not originally intended for audit or areas that have been/are to be audited at some other time.

However sometimes it is better to take notes and follow the trail at a more convenient time or when the audit moves to the area where the trail leads.

What can be examined during an audit?

This will depend very much on the type of environment in which the audit is being undertaken. In some environments such as an office, there may be very little to examine other than documentation, however in aircraft maintenance environments there will be many things that the auditor may examine. In relation to Flight Crew Licensing there is potentially a vast amount of documentation, information relating to people etc. that can be examined by an auditor.

Auditors will need to examine many things in order to obtain the necessary objective evidence of conformance, as they do they should also remain conscious of various problems that may be evident and may provide clues to correct implementation of the management system. Some of these things could relate to the following, however for flight crew licensing this will depend upon the nature of the environment being audited.

Procedures may be examined for Availability, Application, Interpretation, Issue Status, and general employee understanding. However we must be careful not to be too critical of the adequacy of a procedure unless there is evidence of things going wrong due to the lack of detail provided to staff in the procedures. Remember, procedures are provided to communicate company requirements to the auditees staff, and not for the auditors !

Auditors will need to think carefully in advance of the audit of where they might need to go to obtain information from one source to be able to use that information elsewhere in the organisation in order to undertake an effective verification.

In relation to the various requirements contained within Part FCL, the auditor will need to decide the best approach to adopt to establish that the requirement is being met. For some of the requirements this will mean a simple examination of records, however for other requirements the auditor may need to undertake extensive investigations before a high level check list can be answered.

For training it is necessary to validate that the training method enables the desired result to be achieved. This is how competency is assured. Simply providing training does not guarantee competency to undertake a task, and it is always necessary to validate a training process and to verify that those passing through the training process are assessed to establish that the necessary knowledge and skills (competency) have been acquired.

Conducting Interviews and Asking Questions.

From our plan of action we know who we should interview and what information we are probing for. The persons we wish to interview will range from very senior managers through to those who actually undertake the day to day activities in the organisation and clearly the information we seek from the different levels in the hierarchy will be possibly different and will need to be sought after in different ways. We need to be aware not only of who we wish to see, what we are trying to establish and therefore what questions to ask, but we need also to be aware of the psychological aspects of this process.

For senior managers we may adopt a more formal style of interviewing technique than with other employees. Senior staff are more likely to feel comfortable with this style, and it can be modified to suit the circumstances and the relationship between both parties that either exists at the start of the interview or as it progresses. Both the interviewer and interviewee appreciate that time is always the enemy and a well prepared interviewer will be able to extract the necessary information in the shortest time and allow a busy manager to get on with his work.

Interview Techniques

Interview the Right People!

Those responsible

Those doing the work

These are the people who should know.

Those being supplied by the process

You can ask those 'down stream' about their 'supplier'.

We select the right people during the preparation and planning stages.

Generation of check lists ensures that we are well prepared.

Interviewers must remember that everyone is human, and that the interviewee may not fully understand what we are trying to achieve and may have some fears about the process and the eventual outcome. We will achieve far more if the interview is conducted in a relaxed atmosphere and one where neither party feels threatened or intimidated. Good interviewers learn to adjust their style dependent upon the response to the process from the interviewee.

Interview Techniques

Good Auditing Practices:

Ask the right person!
Speak clearly and simply. Use 'local' language.
Look at the person – in the eyes!
Rephrase your question if the auditee doesn't seem to know what you are asking.

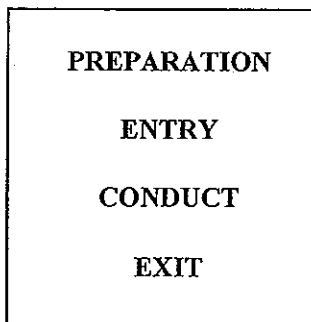
Interview Techniques

Good Auditing Practices:

Don't talk down to anyone.
Be unemotional and impartial
Avoid interrupting an auditee.
Don't look for trouble – Find the facts.
Say "Thank You!"

The interview process:

There are four basic stages to conducting interviews.



Preparation.

Preparation is everything previously addressed for audit/assessment preparation, however, the interviewee also needs to be prepared for the interview process.

Clearly for senior management there should already be a good understanding of what an assessment is likely to involve, and one always hopes that appropriate steps have been taken to convey this to middle management and other company employees and the part that they are expected to play. However, when interviews are conducted with middle management one must expect to spend a short period of time “preparing” the interviewee for the questioning process, introducing yourself and explaining what you are about to do and how you intend to do it.

Entry

The first step in undertaking a successful interview is to arrive on time. Introduce yourself to the interviewee and ensure you record the interviewee’s name and job title when they introduce themselves to you. It is important to spend a short period of time gaining the person’s trust and confidence, if necessary explaining the assessment process and how you intend to proceed. If possible request that telephone calls and other interruptions be blocked and indicate the time that you will need. When the person is seated comfortably begin by explaining the process and give the interviewee the opportunity to ask questions about the process and how the information gained will be used.

It is not good practice to use a tape recorder at such interviews, however if the auditor wishes to use a recording device the auditor must first obtain permission. Explain that you are only recording the interview so that you can pay greater attention to the interviewee and will not have to take detailed notes. Let the interviewee see the tape recorder, switch it on and place it in full view. If there is clearly a negative reaction, or the interviewee is uncomfortable about the use of a tape recorder, don't push the point, switch it off and return to taking notes.

If the audit is being conducted in another organisation, such as supplier or contractor and a guide has been allocated by the company, try to ensure that it is the interviewee that responds to the questions and NOT the guide !

KEYPOINTS

ARRIVE ON TIME

INTRODUCTIONS

RE-STATE PURPOSE

INVITE QUESTIONS

Conduct.

Interviews are conducted by basically asking questions of the interviewee and taking appropriate notes of the responses.

For a well prepared interviewer the previously prepared check list provides a framework for the interview and enables satisfactory responses to be recorded against each question. Only points of interest, variances to previous responses (obtained from previous as well as this interview) and outright deficiencies or nonconformities need to be recorded (Refer to section "Questioning Techniques").

Exit.

Once all questions on the check list have been addressed give the interviewee an opportunity to make any other comments. Now is the time to summarise any concerns or deficiencies that have been noted and ensure that the interviewee agrees with your conclusions and if required signs the official record of findings. If a guide has been present throughout the interview you may require this person to sign such formal documentation. Tell the interviewee what you need to do next (you may need to be taken to another part of the company or be introduced to somebody else in the same department), thank the interviewee for their time and co-operation.

INFORMATION OBTAINED THROUGH INTERVIEWS SHOULD BE VERIFIED BY ACQUIRING THE SAME FROM OTHER INDEPENDENT SOURCES, SUCH AS PHYSICAL OBSERVATIONS, MEASUREMENTS AND RECORDS.

Questioning Techniques.

An auditor needs to be a good communicator. However, communication must be in both directions, and it is necessary for the auditor to seek information by posing a question, and then to await and fully understand the response to that question.

Bad Auditing Behaviour

Asking too many questions
Asking leading questions
Saying you understand when you don't
Answering own questions
Giving insufficient time to answer
Provoking an argument
Subjective opinions
Taking sides
Criticising individuals

**A BAD AUDITOR IS ONE WHO CULTIVATES
ONE-WAY COMMUNICATION.**

Eitherby:

Asking closed questions. (Those requiring only a YES/NO response).

Asking and answering own questions.

Not giving the interviewee sufficient time to respond.

Not asking questions at all, just continuing to chat or expressing opinions.

The auditor must learn how to formulate and ask questions that promote feedback of information, and also how to gather additional information when the initial feedback includes generalisations or distortions or has omissions.

Use of language.

We use language to communicate thoughts and ideas which exist in our brains, however the words we use are only a representation of those thoughts and ideas. We do not communicate the full extent of the image/thoughts/feelings or understanding that exists in our mind, and some people find it very difficult to convey in words what they really mean. Hence the language that we use may not be translated back into the same image/thoughts/feelings/understanding by the recipient. Once the recipient is aware of this problem he/she can work to build up a better picture by testing the information given and retrieving missing information.

Thus communication from an interviewee may include generalisations, omissions and distortions, and it is the job of the interviewer to retrieve this missing information to provide a clearer or more complete representation.

An auditor, must know how to ask a question to obtain information, and where necessary ask further questions to clarify his/her understanding or to obtain further information. Auditors need to develop techniques for asking questions in an easy going and non threatening way, and to work with the information obtained and understand what it means.

Performing the Audit.

Performing the Audit

What can go wrong !!

- Scope too wide for time allotted*
- Plan is too specific for time allotted*
- Sample sizes inappropriately large*
- Inadequate or no check list*
- Failure to follow check list*
- Failure to adhere to schedule*

Performing the Audit



Validation of Findings

- Random Basis*
- Objectivity*
- Factual*
- Agreement*

Be Polite!

Be Professional!

Performing the Audit

***Use easily understood language
Be able to retrieve the facts
Make it constructive and helpful
Make it concise and to the point
Be sure it is true and relevant
No surprises or blind-side attacks
Make sure everyone understands***

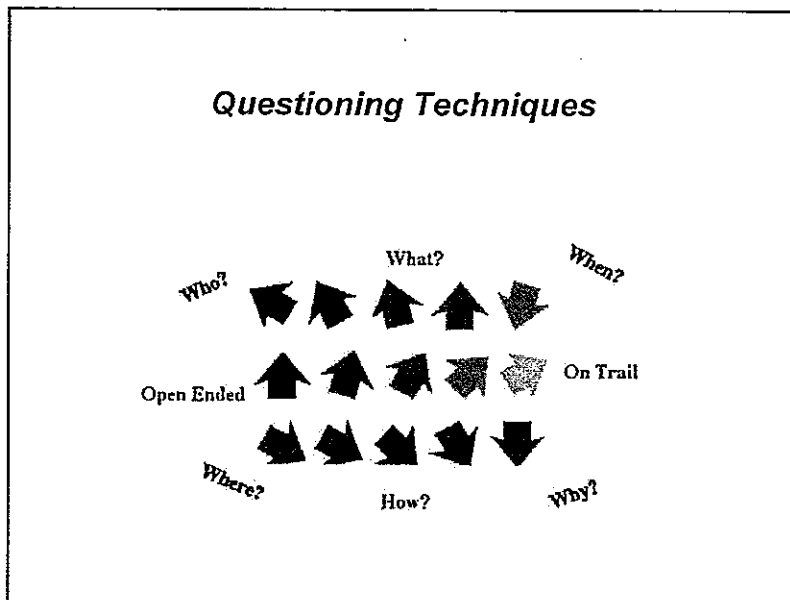
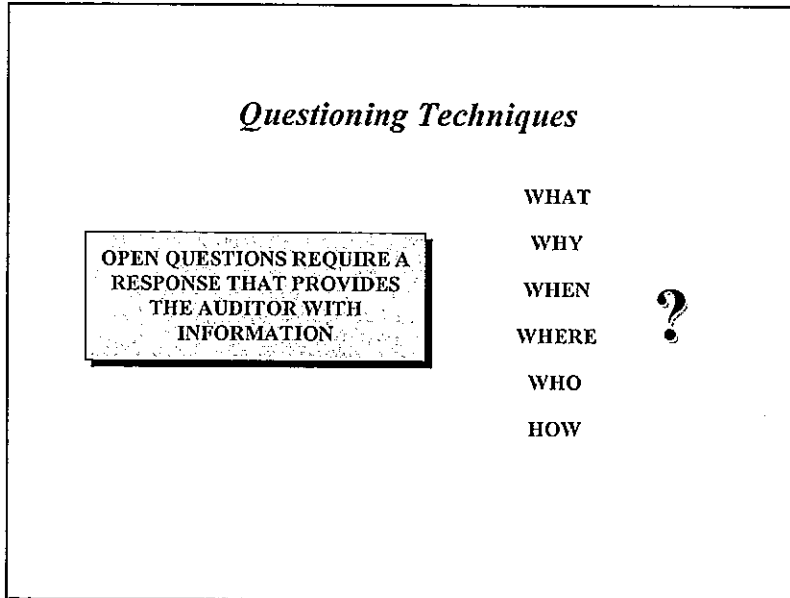
Performing the Audit

Things to Consider – Is it Serious?

***Does what I have found represent a finding?
Sufficient facts?
Critical situations?
Isolated minor discrepancy?
Happening too frequently?
Too many findings?
Formal corrective action versus immediate?***

Use of key words:

Some words are useful to use in a question to force a response. Questions using these words require the auditee to provide information and are known as open questions.



These words may be used to very good effect, but particularly when used with SHOW ME are very powerful in gaining not only information but enabling verification of what is said.

Thus:

Q. How do you store your training records?

A. They are stored in a separate secure area provided with appropriate locked and fire proof filing cabinets.

Q. Could you please show ME!

Investigating the System

Sometimes in order to "investigate" or "test" the system the auditor will use hypothetical questions such as -

What happens if ?

How would you respond when ?

Let us suppose that ?

Occasionally the auditor will not understand the response to a question; there is no shame in requesting the auditee to repeat or expand upon the reply.

I am sorry, I did not quite understand that, could you explain that again please.

The auditor also needs to be systematic. All questions that ought to be asked should be asked; if it is on the check list, then it must be addressed. The auditor should also not be afraid to ask obvious questions, as these can sometimes reveal system weaknesses. However, auditors are often afraid to ask the obvious question for fear of giving an impression that they do not fully understand a process, remember, auditors are not trying to demonstrate superior knowledge or expertise to the auditees but simply trying to verify that everything is hapening in the way that it is supposed to hapen.

Remember also, the power of silent questions. After asking a question the auditor listens to the answer but remains quiet and encouraging the auditee to support the answer with further information, which again may reveal the weakness in a system.

In Summary, we should use various questioning techniques aimed at establishing what is happening and which encourage the free flow of information. Once we have asked a question we must then give the auditee ample opportunity to respond, and most important of all we must listen carefully to the response.

**AUDITORS MUST LEARN TO LISTEN WITH
THE MIND AS WELL AS THE EARS !**

Points to remember

Talk to the person who does the job.
Don't talk down (people are not fools !).
Talk the language of the auditee.
Speak clearly.
Re-phrase the question if not understood.
Don't confuse - ask one question at a time.
Come back if information is not immediately available.

Communication

**A BAD AUDITOR IS ONE WHO CULTIVATES
ONE WAY COMMUNICATION**

By:
Asking closed questions
Answering own questions
Not giving auditee time to respond
Talking continuously
Expressing opinions

The Psychology of Auditing.

It should be remembered that auditors and auditees are only human and that both parties have a clear understanding of what they are trying to achieve.

From the auditors point of view, the intention is to expose any weakness that there may be in the Quality (Management) System, however from the auditees point of view it may be undesirable for the weaknesses to be observed by an external auditor. Hence a game is often played!

People can often feel threatened when the auditors appear, they may fear for their job if deficiencies are found in their area of responsibility. They may be easily upset. Managers in particular may feel that their ability to manage is in question. People do not like being observed carrying out their day to day tasks by those with a critical eye.

If we take the above into consideration, then it is hardly surprising if sometimes the auditor is not made to feel particularly welcome! Or indeed feels that the truth is being hidden.

We should try and remember a few simple rules that relate to the personal side of auditing.

Psychology of Audit

AUDITORS CAN APPEAR THREATENING

**BE RELAXED
BE HUMAN
BE COURTEOUS
DISPLAY INTEREST
REMAIN COOL, CALM & COLLECTED
ACT PROFESSIONALLY**

Auditor and Auditee Tactics.

Auditor Tactics:

The job of the auditor is to clearly establish if working practices conform with the appropriate requirements and to do this certain tactics may need to be adopted depending upon the situation at the time of audit and the degree of co-operation that the auditor sees from the auditees.

In order to remain in control, the auditor should remember the following:

- Be well prepared.
- Be on time.
- Get on with the task.
- Don't argue (*whilst arguing you are wasting valuable audit time*).
- Use the check list (*to remind you what you are trying to verify*).
- Discuss problems when they are found (*to be certain of the facts*).

Additionally, the following are points worthy of note:

If you cannot get the information that you require in one part of the organisation, try to obtain it somewhere else.

If you are faced with non-co-operation from one person, try another.

Verify statements made about other departments/sections in those other departments/sections.

Always look for objective evidence to verify comments made.

Follow trails to the ultimate conclusion (if the trails are relevant to the audit objectives or relate to significant safety concerns).

Return to areas/people if more information, clarification or re-confirmation is required.

Obtain agreement with the audit findings during the audit (and signatures on forms if appropriate).

Auditee Tactics:

It is worth noting that a successful audit is dependent not only upon the skill of the auditor, but also upon the degree of openness and co-operation of the auditees. The auditor's task can often be made more difficult when faced with the following, and a skilful auditor must learn how to successfully handle these situations:

- Argumentative people.
- Outright aggression.
- Time wasters.
- Wafflers.
- Flatterers.
- Senility.
- One upmanship.
- Planned/unplanned interruptions.
- Cook's Tours and long explanations.
- Extended coffee/lunch breaks.
- Pleading of special cases.
- Missing Documents.

Remember, the most difficult people to audit are very often those who have been trained as auditors themselves, they know all the tricks in the book!

Auditing is about learning to talk to and handle people, and it is worth noting that auditors should be selected from those who exhibit the necessary attributes, as well as those who have received professional training.

The Need for Professionalism.

With the above in mind it was recognised in 1987 that a Code of Practice for auditing could be beneficial in promoting a more professional approach. The result was the publication in 1989 of BS7229 British Standard "Guide to Quality Systems Auditing". This British Standard was written in a way which supports the intentions of what was then known as the "Assessor Registration Scheme" (now known as the "Auditor Certification Scheme" administered by the "International Register of Certified Auditors" (IRCA - a subdivision of the Institute of Quality Assurance). BS7229 was subsequently adopted as ISO10011, and has since been re-issued as ISO 19011, and details the 'good practices' that should be adopted by all who undertake Quality or Environmental Management System audits either in a First, Second or Third party sense.

SOME BASIC RULES FOR AUDITORS

PROFESSIONALISM

PLANNING

AVOID SIDETRACKS

SEEK EVIDENCE

AGREE FACTS

CONSTRUCTIVE APPROACH

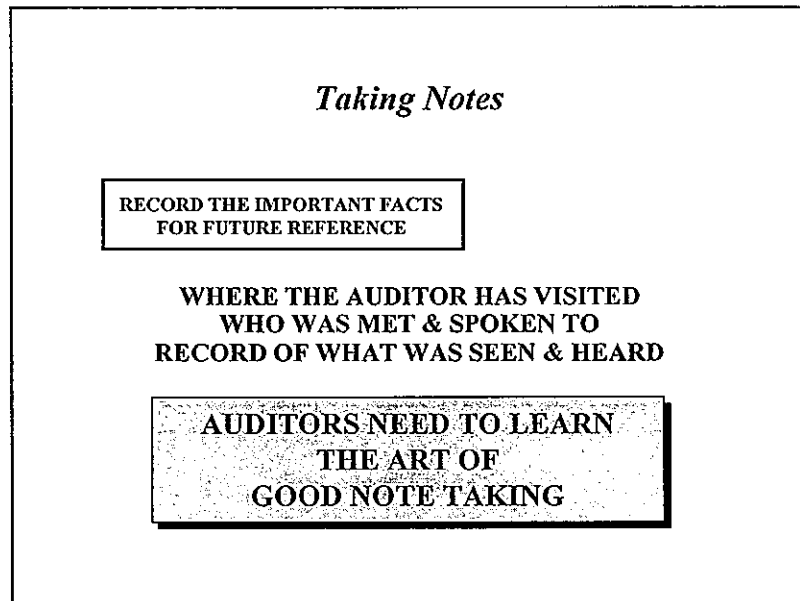
FORMAL REPORT

CHANGE STYLE

DE-BRIEF MANAGEMENT

Recording the Results.

As an auditor conducts interviews, passes through the various departments of an organisation and generally observes working practices, there will of necessity be aspects of operation or comments made by auditees that need to be recorded for further reference. However, just how much should be recorded?



As a minimum the following should be recorded in a formal manner:

Instances of nonconformity to the regulations.

Instances of nonconformity to documented working practices.

These formal records provide the output from the audit and should be recorded on official paperwork. Such formal records will inevitably be termed 'Deficiencies' or 'Nonconformities'. The actual term used may vary dependent upon the auditing organisation. For Internal Audits company auditors invariably use the terminology given above. For external audits undertaken by second or third party organisations the following terms may also be encountered:

Noncompliance Reports (used by regulators)
Corrective Action Requests (CAR)
Discrepancies

The important point to remember is that the auditor must detail clearly and concisely what has been observed and why it is a concern. The auditee needs to know what the problem is before it can be satisfactorily corrected.

However, auditors must remember that they should report only agreed findings based on factual evidence. It is good practice to obtain the signature of the auditee (or auditees representative) on the audit 'nonconformity' report, however not all auditors will do this at the time of finding the facts but may wait until a later time when reviewing the audit results with management or the management representative. However, it is important that the facts are agreed before the auditors move on to another area.

Taking Notes

Please, Please! Take Notes!!!

*For investigation now
For investigation later
For use by other auditors
For use on future audits*

*Legibility
Retrievable*

Taking Notes

*Statements (Admissible)
Document Numbers
Revision information
Names
Location / Places
Dates
Positions*

Taking Notes

Keep People Informed:

- Review Findings Regularly – "Everything looks good here" is a good phrase to use.*
- Keep it Constructive – Criticism we don't need!*
- Show Professionalism – Be precise, attentive, responsive.*
- Create Rapport – Make a friend!*
- Include Appropriate Personnel – Talk to all the right people.*

The "Nonconformity statement" needs to be worded so that it is understandable to those who were present at the time of audit and also to those who were not and who may be involved in implementing corrective actions. It is a means of communication, and if the auditee cannot understand it then the auditor has failed to communicate effectively!

Thus the need to record facts:

What was found
(the objective evidence)

Where it was found
(geographical location)

Why the auditor thinks it is a nonconformity
(reference to a requirement)

Who was present
(only if this is really necessary)

Statements should be clear, concise and meaningful to enable the auditee to fully understand the problem and correct it. Remember that such statements need to be written at the time of audit and so should be short, sharp and to the point. It is normal protocol not to name names in such statements as this could give rise to the allocation of blame without determining the real (root) cause of the problem. It is better to give someone's title rather than name if it is unavoidably necessary.

Nonconformity

**EVACUATION INSTRUCTION SOP 42 ISSUE
"E" IN USE IN 737 SIMULATOR
LATEST ISSUE ACCORDING TO
MASTER RECORD INDEX IS "F"**

The human short term memory is not particularly good at retaining large amounts of data when such data is being rapidly received. In an audit situation we are in a completely new and possible strange environment, it is easy to become overwhelmed by what we see and hear. In this situation it is often difficult to remember all of those interesting things that need to be investigated further at some later time or in another section of the organisation. It is advisable and indeed good practice for an auditor to record this type of data in working notes. Also, notes should be made of who has been interviewed, where in the organisation the audit has been conducted and what procedures or documented working practices or drawings etc., have been examined.

IF ADEQUATE NOTES ARE NOT TAKEN IT WILL BE VERY DIFFICULT TO RECALL WHAT HAS BEEN OBSERVED.

Do not trust your memory, write down information as you go.
Do not clutter your mind with trivia.
Use your check list and record on it if you wish.

Record what needs recording, i.e.:

- Section/area audited
- Person(s) interviewed
- Document numbers and issue status
- Equipment identification
- Product/material identification
- General housekeeping conditions

Make mental notes or note impressions gained of:

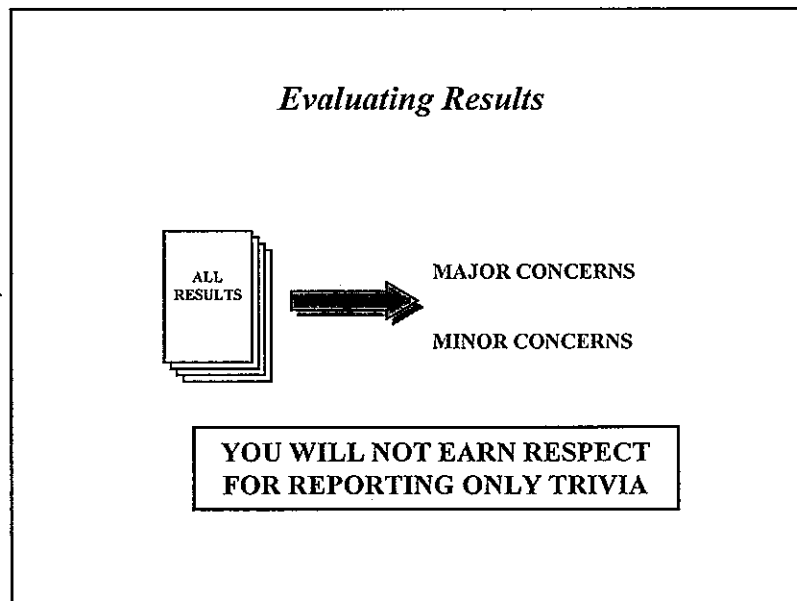
- Workloads
- Attitudes
- Reactions
- Organisation
- Condition of equipment
- Awareness and understanding of procedures

REMEMBER TO LISTEN TO WHAT IS SAID AND OBSERVE AT ALL TIMES, ANALYSE AND RECORD WHAT IS IMPORTANT.

EVALUATING THE FINDINGS

After undertaking an audit there may be a number of audit findings (nonconformities), however some of the findings may be more significant than others, some may be closely related or similar occurrences of the same fundamental problem. The audit team must now undertake an evaluation of all the audit results to identify any areas of concern which will need to be communicated to auditee management. It is not a good idea to read out a large number of audit findings at an audit exit meeting, but much better to group similar findings together and identify any major concerns revealed by the audit, i.e. to identify the big picture revealed by the audit.

If there are very few findings of any real significance then it is probably not a good idea to suggest that these are of major importance, but instead tell the auditees that it is basically good news and the audit sample taken has not revealed any findings of significance.



This evaluation should be undertaken at the end of the audit and before presenting the results to auditee management. Remember, management are not interested in trivia, they need to know what the main problems are.

Some organisations categorise nonconformities as major or minor or attach a numerical indicator of severity i.e. Category 1, 2 or 3. Although there are no formal definitions as such in any ISO standard the following are typical examples of definitions that are used by many audit authorities:

Major Nonconformity

A SIGNIFICANT NON-COMPLIANCE WITH A MANAGEMENT
SYSTEM REQUIREMENT

OR

A FAILURE OF, OR COMPLETE OMISSION OF A MANAGEMENT
SYSTEM REQUIREMENT

OR

A SIGNIFICANT NUMBER OF MINOR NON-COMPLIANCES
CONCERNING THE SAME MANAGEMENT SYSTEM
REQUIREMENT

It is important for an auditor to differentiate between things that are of a serious nature and those that may be less so, however the above definitions as above are considered to be somewhat subjective and could result in much debate at the time of audit, particularly if to receive a 'major' nonconformity could result in the lack of formal approval or loss of an order.

In some instances an auditor may be given information or make an observation that whilst not a non-conformance as such, indicates that potentially one might arise if the situation were not addressed. Auditors often use the category "Observation" for such instances, however it is felt that unless hard factual (objective) evidence of nonconformity is found by the auditor then one does not exist. The term 'observation' should not be used to describe a lower category of nonconformity.

EASA Part OPS ARO.GEN.350 "Findings and corrective actions" identifies the Levels of findings and the corrective action requirements that must be followed.

EASA
Part OPS ARO.GEN.350
Findings and Corrective Actions

A level 1 finding is any significant non-compliance with the applicable requirements of Reg (EC) No. 216/2008 and its Implementing Rules, with the organisation's procedures and manuals or with the terms of an approval or certificate or with the content of a declaration which lowers safety or seriously hazards flight safety.

EASA
Part OPS ARO.GEN.350
Findings and Corrective Actions

A level 2 finding is any non-compliance with the applicable requirements of Reg (EC) No. 216/2008 and its Implementing Rules, with the organisation's procedures and manuals or with the terms of an approval or certificate or with the content of a declaration which lowers safety or seriously hazards flight safety.

EASA
Part M Subpart I

A level 1 finding is any significant non-compliance with Part M requirements which lowers the safety standard and hazards seriously the flight safety.

A level 2 finding is any non-compliance with the Part M requirements which could lower the safety standard and possibly hazard the flight safety.

No level 3, No Observations.

Audit Exit

Following an audit an Audit Exit meeting should be held at which the auditor(s) will provide the auditees with an overview of the audit team findings. It may not be necessary to go into great detail in respect of each audit finding, however the audit conclusions should be clearly and concisely conveyed to auditee management in a form that is understandable and without undue emphasis on relatively trivial findings. It is advisable to provide the summary first and to follow this with the details if they are required by auditee management.

In many cases auditee management will wish to know of significant findings or of specific audit concerns resulting from grouping of findings into categories.

Auditee management may require all details resulting from the audit, including all individual findings (this is their prerogative), however it is advisable to keep the Audit Exit meeting relatively short and ultimately provide full details of audit findings in a formal report. In most cases the audit exit meeting will merely convey audit findings in the form of completed audit report forms for auditee review and action.

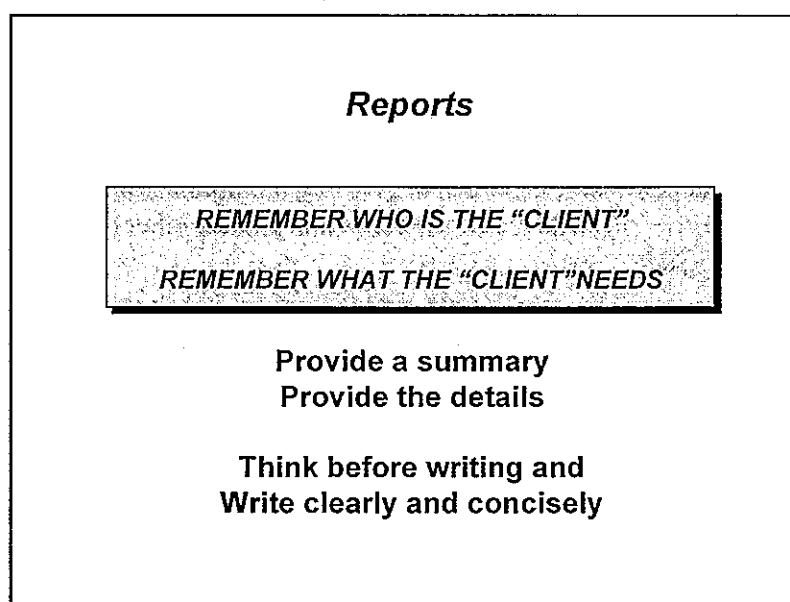
If the company system requires it, the auditor(s) should provide a final audit report for auditee management, incorporating the detail from all audit findings together with any conclusions.

Closing Meeting

Opening Remarks & Thanks
Attendee List – Pass around for signatures
Review Audit Objective & Scope
Audit Restrictions / Limitations
Tell of GOOD things you saw
Summary of Findings (Main concerns / weaknesses)
Nonconformities
Questions
Corrective action & follow-up process

Formal Reports

Following a major audit it is good practice to provide the auditee organisation with a formal report detailing findings and conclusions of the audit. The nature of such reports will vary depending upon the type of the audit undertaken, however the main purpose of such a report is to clearly convey to company management the findings and ultimate conclusions of the team. It is important to remember that the report should hold no surprises, and it should reflect accurately what was presented at the exit meeting.



Main Content for an Audit Report

Report identification
Purpose, objective and scope of the audit.
Details of the auditors, dates and part of organisation audited.
Identification of the reference documents against which the audit was conducted
(*Regulations, Management System, procedures, contracts, etc.*)
Summary of audit findings.
Details of audit findings (nonconformities) and supporting evidence.
Conclusions of the audit, judgements as to the degree of compliance.
Recommendations for follow-up of corrective action.
Distribution.

The audit report should be signed and dated by the lead auditor, and distributed as necessary. For second party assessments that are part of a supplier selection process it may be necessary for the team leader to prepare a version of the report for use within the purchasing organisation, and for such reports an Executive Summary may be appropriate. Such summaries should be prepared with the busy executive in mind and should clearly and succinctly convey:

<p style="text-align: center;">Conclusions An overview of findings Recommendations</p>

For both internal audits and assessments of external organisations it may be company policy to require auditors to provide recommendations for overcoming non-conformances found. Unless this is the case auditors should refrain from becoming too involved with the corrective action process other than verifying effectiveness of such.



SINGAPORE AVIATION ACADEMY

Regulatory Approval and Oversight



**Regulatory Approval
&
Oversight**

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Follow-up and close out of corrective actions

AUDIT RELATED TERMINOLOGY (Not definitions):

<p>Audit A term used to describe the physical examination of actual practice, or the results achieved, for an activity and the comparison with requirements detailing what should be done and how it should be done, or the results that should have been achieved.</p> <p><i>Audits are not undertaken to verify that actual practice, or an item, is acceptable in order to allow continuation of the process. Audits are undertaken in order to provide unbiased objective data to enable judgements to be made about the overall acceptability of a system, process or product.</i></p> <p><i>Auditing is primarily a feedback mechanism for the purpose of providing confidence that a process or system is capable of providing acceptable outputs or outcome.</i></p> <p><i>System / Process / Product Audit</i> Audit to verify the effective implementation of a system / process or that a product complies with requirements.</p> <p><i>Internal Audit</i> Audit undertaken by an organisation on its own system, process or product.</p> <p>Audit client Organisation or person requesting an audit and requiring the audit information.</p> <p>Audit criteria Set of policies, procedures or requirements that the auditor is verifying conformity with.</p> <p>Audit findings Facts obtained by the auditor indicating conformity or nonconformity with the audit criteria.</p> <p>Audit Scope Those parts of the organisation that are to be subject to audit activity.</p> <p>Auditee The organisation or person being audited.</p> <p>Auditor A person with the authority to undertake an audit.</p> <p>Inspection The true meaning relates to the physical inspection of a tangible item for the purpose of verifying that it meets the specified requirements, and is suitable for continued processing or delivery.</p> <p><i>Note: The term "inspection" is often applied to the activities undertaken by a regulatory 'inspector'. This activity is better known outside aviation as "Audit".</i></p>	<p>Nonconformity A generic term used to describe the factual evidence that indicates that there is a situation that does not meet specified requirements.</p> <p>Noncompliance A term used to describe the factual evidence that indicates that there is a situation that does not meet regulatory requirements.</p> <p>Objective evidence Evidence that exists such as records, or other information including observations. (<i>Statements made are not objective evidence.</i>)</p> <p>Quality A totality of features or characteristics of a product / service that satisfy customer requirements / expectations, or is fit for the intended use. (<i>Good quality implies features and characteristics that meet defined requirements</i>)</p> <p>Quality Assurance The means of providing confidence that quality requirements will be met.</p> <p>Quality Control Mechanisms used, such as checks or tests, that are performed to ensure that requirements are met.</p> <p>Quality Management The means by which an organisation manages its activities to achieve its quality objectives.</p> <p>Quality Objective A specific target or objective that management wish to meet in relation to product / service quality.</p> <p>Quality Policy A statement setting out management's overall intentions in relation to the quality of products / services.</p>
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Oversight Management

Obligations of the State - Chicago Convention.

Regulatory Approval & Oversight

Auditing as an integral part of Oversight

Auditor competence

Management of the Approval Audit Process

Audit Records

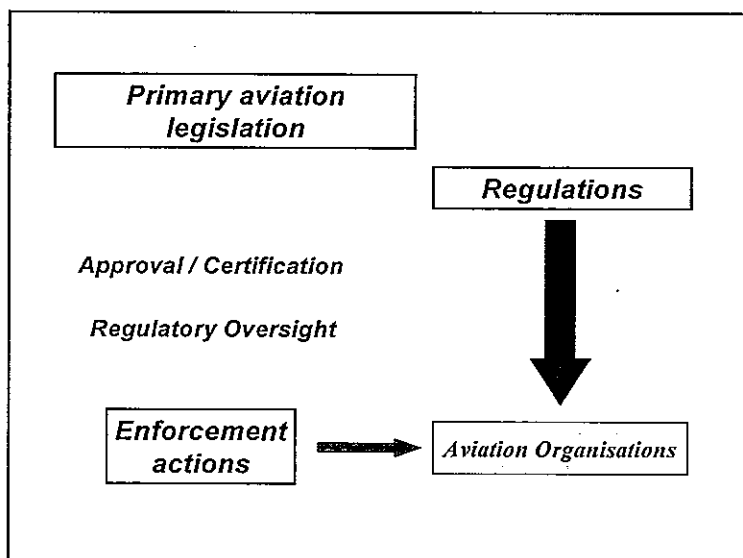
Standardisation of auditing

Applications of auditing within regulated organisations

Obligations of the State - Chicago Convention.

The Chicago Convention was signed on 7 December 1944 by 52 States and the International Civil Aviation Organisation came into being on 4th. April 1947. In October ICAO became a specialised agency of the United Nations. (As at 17th May 2006 there were 189 contracting states). ICAO's aims broadly relate to Standardisation through the promulgation of Standards and Recommended Practices (SARPS), provision of CNS/ATM facilities, Regional Planning, Facilitation of Air transportation, Economic matters and Technical Cooperation for international development and the international unification of aviation laws.

In accordance with the Convention a State has complete and exclusive sovereignty over the airspace over its territory but agrees to certain principles and arrangements relating to the minimum standards, procedures and practices that need to be adopted in order to allow for safe and orderly civil aviation operations within its airspace. It is therefore responsible for ensuring safety within its airspace and has an obligation to provide safety regulations, air navigation equipment and aviation operations compliant, as far as possible, with ICAO requirements. Safety regulation of civil aviation is a national responsibility and Contracting States need to establish and implement systems that enable them to meet their international obligations. ICAO Standards and Recommended Practices (SARPS) need to be reflected within the laws of States, and a contracting State will need to enact legislation that will provide the necessary framework for discharging its obligations. This is known as "Primary Aviation Legislation". The legislative framework will then allow for the development of the necessary civil aviation regulations that in turn will ensure that civil aviation operations are conducted in accordance with the minimum requirements contained within the SARPS and the relevant Annexes to the convention.



The ICAO Annexes:

Annex 1 - Personnel licensing

Annex 2 - Rules of the Air

Annex 3 - Meteorological Service for International Air Navigation

Annex 4 - Aeronautical Charts

Annex 5 - Units Of Measurement To Be Used In Air And Ground Operations

Annex 6 - Operation of Aircraft

Annex 7 - Aircraft Nationality and Registration Marks

Annex 8 - Airworthiness of Aircraft

Annex 9 - Facilitation

Annex 10 - Aeronautical Telecommunications

Annex 11 - Air Traffic Services

Annex 12 - Search and Rescue

Annex 13 - Aircraft Accident and Incident Investigation

Annex 14 - Aerodromes

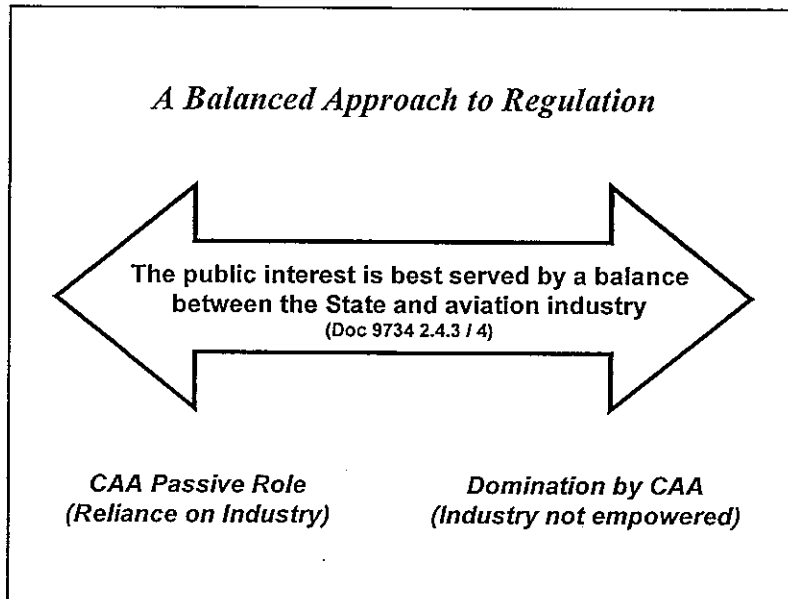
Annex 15 - Aeronautical Information Services

Annex 16 - Environmental Protection

Annex 17 - Security: Safeguarding International Civil Aviation Against Acts of
Unlawful Interference

Annex 18 - The Safe Transport of Dangerous Goods by Air

ICAO actively promotes a clear separation of responsibilities between the provision of aviation related services and regulation, and in the case where the state provides some aviation related services effective regulation will only be achieved if there is a clear separation of responsibilities and the regulatory function is able to act in a totally independent fashion.

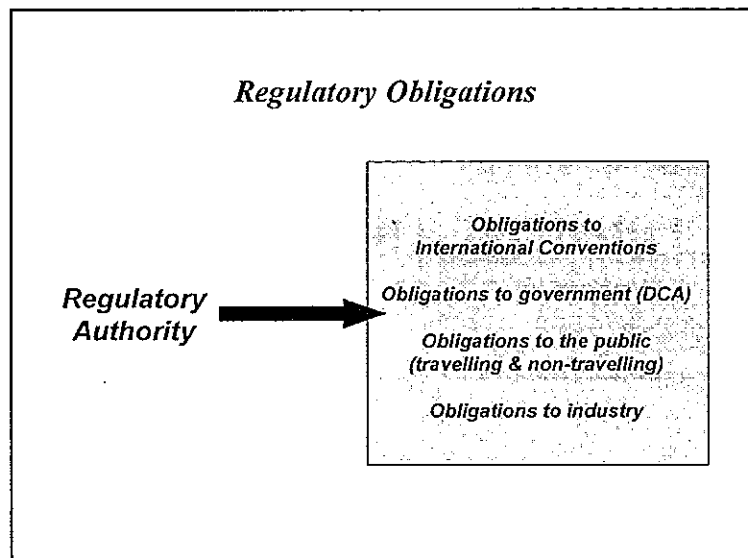


There should also be a balanced approach to regulation. If the regulator is too prescriptive then industry is simply under the control of the regulator with little freedom to act and so becomes dependent upon the regulator with consequent possible lack of innovation and efficiency and consequent high costs to the travelling public and / or tax payer.

If, on the other hand the regulator simply allows the industry to work with no clear regulations and a lack of competent persons undertaking oversight activities, then commercial considerations could assume far greater importance to the safety of the travelling public.

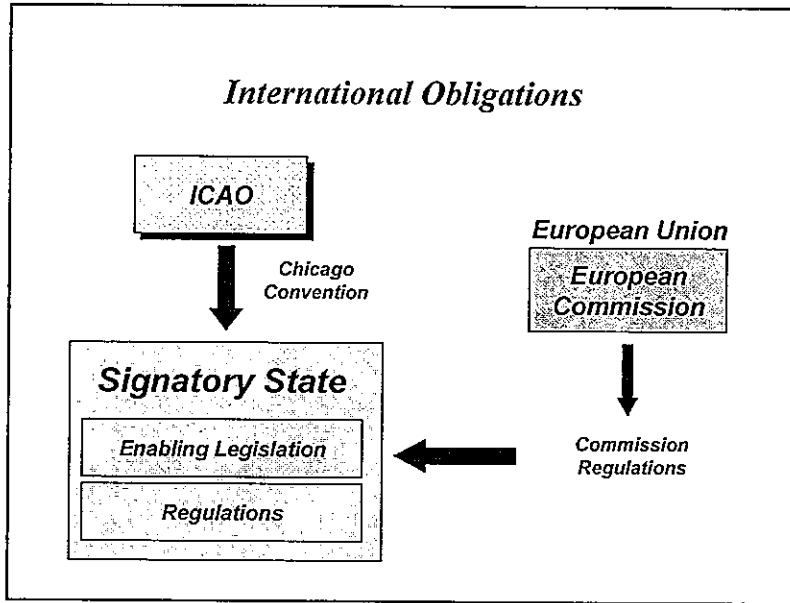
A national regulatory organisation has obligations:

1. An obligation to the State government to ensure safety in aviation, and to discharge the State's international obligations to the Chicago convention that the state has signed up to.
2. An obligation to the travelling public to provide for safe and efficient public transport systems.
3. An obligation to provide for effective regulation of all parts of the industry that provide support to the other parts.



The regulatory authority will need to have the support of a well constructed regulatory framework, together with a mandate to take the necessary actions to ensure that organisations comply with regulations. They need to have the legal ability where necessary to take enforcement action. Regulators will need to provide rules that organisations must meet to satisfy their national primary aviation legislation. In the U.K. such rules are provided, together with guidance material, in the form of Civil Aviation Publications (CAPs). The rules will need to strike a balance between “prescription” (where the regulator effectively takes ownership of the means to meet the regulations by stating exactly what must be done), and the broad setting of “objectives” (where the regulator is only concerned that an objective is met and not how it is met).

Within Europe EU States not only need to meet their obligations in respect of the ICAO Convention, but they also need to comply with EU law. There are also States outside of the EU that have elected to enact EU laws into their own national law, whilst there are also some that have not done this but generally adopt EU laws as good practice without the support of the legislative framework.



Regulatory Approval & Oversight.

Organisations that wish to provide certain products and/or services for which they need to hold formal regulatory approval (or sometimes certification) need to make a formal application to the appropriate regulator, In order to be able to grant an approval the regulator will need to have confidence in the organisation's ability to manage those processes the subject of regulation in a fully effective manner such that the regulator has the 'assurance' of management systems implementation and therefore in the ability of the organisation to conduct its activities in a manner which will result in the requisite levels of safety or airworthiness. Various background checks may be undertaken by the regulator such as financial checks to establish that the organisation is set up on a sound financial basis, and checks on key personnel to be certain that they have the necessary experience and competence to perform their regulatory related duties and discharge their accountabilities.

In order to gain this assurance the regulator will first need to see evidence that the organisation understands the regulations and their responsibilities in relation to these and has put in place the necessary processes that are designed to meet the regulations. Such evidence may be required in a particular form to suit the regulation and the regulator. Operators will produce a "Flight Operations Manual", and many maintenance organisations are well used to the idea of producing a "Maintenance Management Exposition" or MOE which will need to be constructed such that specific and relevant information is provided to the regulator to enable the regulator to understand the organisation (formal structure, reporting lines etc.) and to be able to clearly see what processes (mechanisms) have been put in place by the organisation that are designed to enable the organisation to conduct operations/ maintenance activities fully in accordance with the applicable regulatory requirements. Often there is also a requirement for a "Quality Manual" that sets out the practices that the organisation will employ to manage quality related processes/ activities.

The process of reviewing this documentary evidence is often termed a "Document Review". Such reviews should be confined to high level documents only, however often there will be a need to include lower level documents in this review in order to obtain the necessary confidence that appropriate processes have indeed been developed.

Once this document review has been undertaken and confidence has been established the regulator will then need to visit the organisation to see that the declared processes are indeed being operated and are effective in achieving the desired objectives.

This two stage process is the organisational approval assessment process.

Once formal approval has been granted the regulator will then need to implement an ongoing process of visits to verify continued implementation of the declared processes and regulatory compliance. It is normal for such an ongoing process to verify implementation of all necessary regulations in all relevant areas of the organisation over say a two year time frame. This process may be termed on-going surveillance or regulatory oversight.

An oversight or surveillance audit programme will need to be developed by the regulator for each organisation to which approval has been granted, and will need to be responsive to the results of oversight visits and the organisations general performance against regulatory objectives.

The regulatory organisation may need to be able to demonstrate effective implementation of its regulatory oversight processes to international organisations such as ICAO in order to demonstrate compliance with the international obligations of the state.

The Approval Team Leader.

It is normal practice to identify an individual who will have the full responsibility for the planning and conduct of this approval process and for reporting the results to the senior management function in the regulatory organisation responsible for ultimately deciding on the grant of approval, further regulatory actions and/or continued operation of the organisation. This individual is often termed the approval Team Leader.

ICAO Documents 9734 & 9735.

ICAO provide a Safety Oversight Manual (ICAO Doc 9734) which provides the basic mechanisms for a Contracting State's overall safety oversight responsibilities. This manual identifies the **"8 critical elements of a safety oversight system"**

- The need for primary aviation legislation,
- The need to support this with specific operating regulations,
- An effective State civil aviation system and safety oversight functions,
- Qualified & trained technical personnel,
- Technical guidance, tools and the provision of safety-critical information,
- Licensing, certification, authorisation and approval obligations,
- An effective Surveillance process,
- The resolution of safety concerns.

In the event that safety oversight reveals that there are significant weaknesses which have safety implications then the State's regulatory function should have the necessary enforcement mechanisms available within the legal framework to ensure compliance where a service provider continues not to satisfy the rules.

A Safety Oversight Audit Manual (ICAO Doc 9735) provides ICAO USOAP auditors and Contracting States with guidance and standard auditing procedures for the conduct of safety oversight audits together with auditors check lists.

Auditing as an integral part of Safety Oversight.

Auditing is an essential element of an overall regulatory oversight programme. It is the means by which the regulatory organisation obtains objective evidence of the compliance of an organisation with regulatory requirements and which, together with other evidence relating to safety performance provides the regulatory organisation with the information to justify the decision to allow the organisation to provide its services.

An “audit” is a systematic and independent examination conducted by, or on behalf of, a regulatory organisation to determine that what is happening in an organisation complies with the applicable regulations and whether they are implemented effectively and enable the achievement of the required results.

In planning and implementing regulatory oversight a regulatory organisation will need to plan for auditing activities to obtain sufficient information about organisations under its jurisdiction and will then need to provide the necessary competent technical and managerial resources to undertake these planned audits and react accordingly to the results achieved.

It is the responsibility of a State that is a signatory to the Chicago Convention to ensure that its aviation regulatory function(s) have an adequate organisation and technical competence and capability to undertake the necessary regulatory oversight activities. This could be a problem for small States where there is a very limited aviation industry from which to draw upon for the necessary technically competent resources, an in such cases it may be necessary for the State to utilise staff on a temporary secondment from industry basis (providing that true and effective independence is not compromised) or to work with other States on a regional cooperative basis to support the State's own limited resources with competent staff from other States (or industry in other States).

Within the aviation industry there is often confusion between the terms "Audit" and "Inspection". The simple answer as to the difference between these two terms is as follows:

Regulatory staff undertaking oversight activities often refer to themselves as "Inspectors" and therefore they consider that the work they perform is "Inspection". In industries other than aviation such activities would be termed "Audit".

Within an industrial, manufacturing or aircraft maintenance organisation the act of "Inspection" is used to describe an activity undertaken to verify conformity with a specification or standard and is a necessary part of the control process for producing an item or product / service. Whereas an audit is performed only fairly infrequently to establish that processes are being undertaken in accordance with process requirements communicated in some form of procedure or instruction. Auditing is not a part of the normal routine process control activities, and an organisation does not use auditing as a means of checking that a product / service conforms to requirements except on a random basis where a general level of assurance in product conformity is required.

There is widespread acceptance that if undertaken correctly audits can provide a very effective regulatory verification technique.

Regulatory organisations will need to develop a comprehensive safety regulatory oversight audit programme. This programme will need to be responsive to the safety situations that the regulator is aware of in the regulated organisations, so for example there may be aspects or areas of safety concern due to a high number of incidents that have occurred, or the general safety performance noted over a period of time. The audit programme therefore needs to be both pro-active in relation to concerns that the regulator has and also reactive to the situation that is observed / experienced.

Auditing should therefore be focused onto areas of concern or possible weakness and not simply undertaken in accordance with a programme that takes no consideration of the real world situation. Auditing should also be comprehensive in that it should not leave out activities or organisations simply due to the lack of resource or interest within the regulator. All organisations under the jurisdiction of a regulatory organisation will need to be included in the oversight audit programme, with more audits being undertaken in those where the regulator has concerns rather than where there is a high degree of confidence. Regulatory organisations will need to ensure that audit programmes are comprehensive and must decide which arrangements, elements, services, products, physical locations and organisational activities are to be audited within a specified timeframe and hence will need to be included in the audit programme. There will also need to be a suitable audit follow and close out mechanism for audit findings.

Auditor Competence.

The competence of those conducting audits is important if an audit 'client' is to have confidence in the results. Auditor competence is based on a demonstration of: a combination of personal attributes as well as the ability of the auditor to apply their knowledge and skills resulting from their educational background, industry and audit experience.

Auditor personal attributes include amongst others the ability to be ethical, open minded, diplomatic, observant, perceptive, versatile, tenacious, decisive, self-reliant, objective, professional, etc. etc.

All persons involved in regulatory oversight activities, including management activities, should have the appropriated education, training, technical and/or operational knowledge, experience and qualification relevant to the specific duties they have to perform. Personnel involved in managing and undertaking oversight auditing activities should have appropriate technical and/or operational experience and specific training matching the experience and training of the organisations that they are regulating (i.e. personnel with extensive operational experience within an airline, aerodrome etc.)

A regulatory organisation will need to establish processes to ensure adequacy of those involved in regulatory oversight activities by specifying the minimum level of education for the job, the amount, type and diversity of required experience. Appropriate job descriptions will need to be provided together with staff selection criteria derived from those job descriptions. Appropriate training will need to be provided.

Those who manage or conduct regulatory audits will need to have the necessary competencies, acquired through suitable training and/or experience. These competencies include:

- The knowledge and understanding of the requirements against which regulatory audits are undertaken,

- Current best practice audit / assessment techniques,

- Audit process management skills,

- Audit team leadership skills

Auditors should have some generic knowledge and skills to act as an auditor or audit team leader together with knowledge and experience in the appropriate management system discipline together with:

- a) an appropriate education for their intended field of auditing coupled with appropriate knowledge and skills,
- b) work experience relating to their intended field of auditing.

In particular audit team leaders should also have additional knowledge and skills in team / audit leadership to facilitate efficient and effective conduct of an audit, e.g.

- audit planning,
- communication,
- organising and directing,
- reaching conclusions,
- preventing and resolving conflict,
- audit reporting.

Auditors and audit team leaders should be periodically evaluated for competence against appropriate criteria relevant to the auditing activities that they are required to undertake.

AUDITOR QUALITIES

- Confident*
- Diplomat*
- Personable*
- Inquisitive*
- Good Listener*
- Versatile*
- Constructive*
- Objective*
- Resilient*
- Analytical*
- Familiar with Quality System*
- Professional*

Auditor Characteristics

*To get along well with other staff
(To be respected)*

Enquiring & logical minds

Prepared to undertake lengthy investigations

To remain Objective and not Subjective or "opinionated"

Major Problems with Auditing

Auditors not given direction by Management

Auditors viewed as a "Police Force"

*Auditors believe that they are an elite group of
"Quality Specialists"*

Management and staff hide facts from the auditors

Management of the Approval Audit Process.

An audit will not always lead to a formal request for corrective action. Auditing is concerned with the gathering of factual information for the auditor's 'client', and what the client chooses to do with the information is the client's business. Many auditors feel that it is their right to demand corrective action, forgetting that they are there only to serve the needs of the 'client' and the client will decide what is to happen next.

Hence there are two separate sub processes in relation to any auditing activity:

The audit itself - gathering information for the auditor's 'client'

The corrective action process - which is driven by the client and may not even involve the auditor.

(See ISO 19011)

In relation to regulatory approval and oversight, it is important to recognise that it is the regulatory organisation that is granting approval on behalf of the State and not the regulatory organisation's inspectors. Hence there is a need for a designated management function within the regulatory organisational structure that will act as a focal point for this approval, and continued approval decision making process (within EU states this decision making process is undertaken in relation to certain approvals by EASA and not individual States). This function is effectively the 'client' or 'customer' of the regulatory oversight process. Auditors / inspectors have a responsibility to provide this function with the necessary information together with recommendations to facilitate decision making in respect of the award of approval or continued approval (in some cases it may also relate to certification decisions, i.e. ATM service provider certification under SES legislation, or Certification of Aerodromes). The final decision must be made by a person in the regulatory organisation who will use all available information concerning the compliance, financial status etc. of an organisation to arrive at a conclusion as to whether approval is granted or if any further actions are necessary before it may be granted.

This is a very necessary function to ensure that there is an ultimate accountability within the regulatory organisation for decisions on approval / certification, or if action is to be taken by the regulator to revoke an approval or impose conditions if the organisation fails to comply at some future date and takes the necessary action to restore full compliance.

Auditors / inspectors must provide this focal point with an audit report, which will be used to help reach a decision on approval / certification.

Auditor independence and impartiality is necessary in any audit process, and for safety regulatory oversight audits it is necessary to ensure that the audit process is as independent and impartial as possible. By having such a focal point responsible for approval / certification decisions it helps to guard against the possibility of pressure being brought to bear on auditors / inspectors to award approval / certification. This can sometimes happen, and for a team leader it is often reassuring to be able to say at an audit Exit meeting that it is only in his / her power to provide the audit facts to the regulatory organisation and it is the regulatory organisation that takes the final decision based on all information concerning the organisation.

This is particularly important where an external agency (or recognised organisation under SES) is used to undertake the audit activities).

For the conduct of audits that form part of an "Approval" or "Certification" process there are two defined stages that need to be undertaken.

Stage 1: A review of the documentary evidence provided by the organisation to demonstrate that it has adequately addressed the appropriate requirements in its documented system. This is sometimes referred to as a "**Desk Top Audit**", however it is not an audit at all but a full and formal review against a full set of requirements that the organisation is required to meet. During the stage 1 review the regulatory organisation is looking for clear signs that:

- a) the organisation understands the regulations that it is setting out to meet,
- b) the organisation has developed processes that look as though they have been designed to meet the regulations.

Stage 2: An on-site audit to establish that the organisation is implementing its documented system. This is a true audit that involves sampling of activities, documents and records.

The Stage 2 verification will need to involve one or a series of on-site audit visits to the relevant site(s) of the organisation, dependent upon the size of the organisation and the state of maturity of its systems. When the audit has been satisfactorily completed, the audit team leader will need to provide a report to the management function in the regulatory organisation with the responsibility and authority for making decisions on approval / certification.

Following Stage 2 the regulatory organisation will make a decision concerning the award of Approval (or Certification), however this may also depend upon the effective response to any nonconformities that were found during the Stage 2 audit. From then on "Ongoing Oversight" will need to be undertaken by the regulator in a planned and systematic way to verify continued compliance.

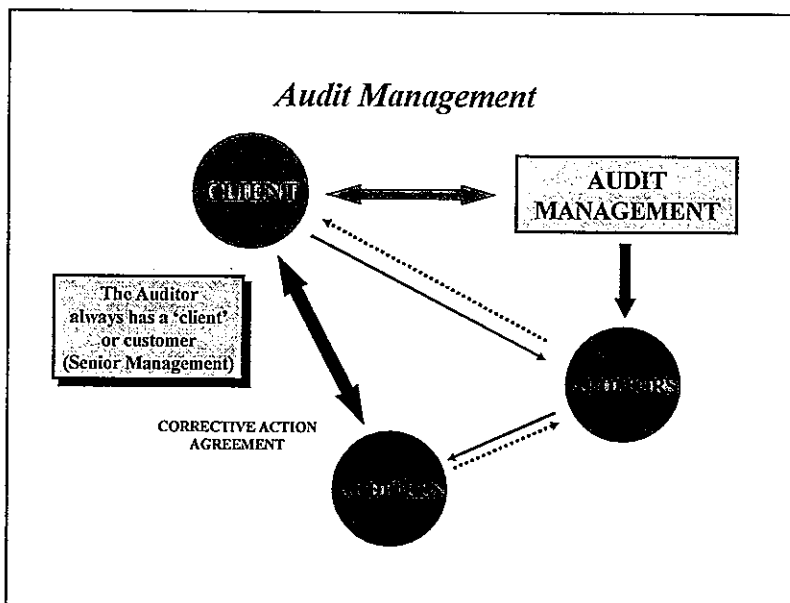
Note: As a prerequisite to any form of Approval or Certification assessment of an organisation it is commonly accepted that it is necessary for the regulatory management system to have been in operation for at least six months in order for there to be sufficient evidence of the effective operation of the system before any formal auditing is undertaken.

Audit process management.

Audits should not be undertaken merely to keep auditors employed! Audits should be undertaken when there is a need for information in order to facilitate decision making. However, in many cases, particularly for internal audits, it is the auditors themselves who decide what should be audited and how frequently. This is clearly an inadequate approach, however if management take little or no interest in auditing then it is inevitable that those who appreciate the need, or are enthusiastic about the task will drive the process in the way that they feel best serves the need of the organisation. The end result is an audit system that provides information about aspects of organisational performance that are of little or no concern by senior management, whilst important aspects are left uninvestigated.

Management should be in full control of the audit process, participating fully in planning audit programmes, receiving and analysing audit results, and determining the need for, and timescales of, corrective actions. It should not be the task of the auditors to decide what is important to be corrected and how quickly it should be actioned. Unfortunately, in many organisations the auditors assume that they have the responsibility and authority to require (demand) that corrective actions are undertaken in response to audit findings. In these situations auditors are beginning to drive organisations rather than management. If management do not participate in the audit process it will do very little to serve their needs.

We need to fully understand why auditing is necessary, and to set up a mechanism whereby it can be steered by management to serve their needs. A suitable model is as follows:-



All auditors have a "client", that is an individual or an organisational function that requires information.

Auditors, and the audit process need to be managed on behalf of the client by a function termed "Audit Management".

It is the responsibility of Audit Management to liaise with the client and determine what are the audit needs of the client (what information is required by the client). It is then possible to programme audits to provide this information and arrange for suitable audit resources.

It must be recognised that for certain information auditors with very specialist knowledge and experience may be required.

Once the audits have been undertaken and the information provided to the client, it is then the responsibility of the client to decide if corrective action is necessary and by when. They will either need to liaise directly with the audited organisations or request the auditors to undertake this task on their behalf. By this means management may remain fully in control of the audit mechanism, the auditors providing information as required.

For a regulatory authority the 'inspectors' are undertaking audits on behalf of the function in the authority that makes decisions on approval and the continued operation of an organisation. However, in many cases the regulatory organisation may delegate certain 'powers' to the auditors / inspectors. It is common for the auditors to be given the responsibility and authority to plan audit oversight programmes for the organisations that have been allocated to them, and they will be the ones who determine from the audit results if corrective action is required and an appropriate timeframe. However this delegation of responsibility & authority should be as a result of formal decision making on the part of regulatory management and not simply an 'understood' or 'default' situation as a result of lack of managerial control over the regulatory audit process.

Audit oversight programmes.

A focal point in the organisation should be identified to manage the entire audit activity. This individual should be knowledgeable about auditing and capable of managing an activity that may involve staff at all levels in the organisation.

The prime responsibility of such a focal point is to manage the audit oversight programme on behalf of senior management and to ensure that adequate competent resources are used.

A pool of audit staff should be trained and made available to Audit Management for the purpose of undertaking the oversight audit programme. How many is dependent upon the size of the organisation and how often we wish each member of the audit pool to be involved in audit activity.

Audit Management should develop, in conjunction with Senior Management, a suitable audit oversight programme (usually on an annual basis). As soon as possible the individual auditors should be identified for each audit activity. The audit pool should include those with appropriate specialist knowledge to ensure all areas of organisations are subject to effective oversight audit activity.

THE LEVEL OF AUDIT ACTIVITY SHOULD BE DETERMINED BY THE NATURE AND STATUS OF IMPORTANCE OF COMPANY OPERATIONS AND BY CONFIDENCE IN SYSTEMS IMPLEMENTATION.

This does not however preclude the additional activity of carrying out unscheduled or special audits, which may become necessary due to the occurrence of significant problems in an organisation, regulatory concerns due to high incident rates, complaints received from the general public etc.

In such instances the oversight audit schedule should be amended to show the inclusion of additional audits and appropriate notice of intent provided to the organisation(s) concerned (although in some instances unscheduled audits may be undertaken without notice). Consideration should also be given to the selection of auditors who may require more specialist knowledge for such audits as it is not always the case that an individual inspector will possess all of the necessary technical knowledge to be competent in undertaking audits in all areas of some organisations.

Allocation of audit tasks.

Auditors should be nominated for each individual audit who then have a prime responsibility to ensure successful completion of the audit task, which includes planning, communication with the organisation, conduct of the audit, and follow-up as required.

Audit Management should ensure that relative responsibility for audit 'close out' are fully understood, particularly when this does not involve the auditor who undertook the original audit.

The auditor is responsible for planning the audit visit, providing the organisation to be audited with appropriate advance notice and a suitable audit visit schedule, indicating key staff that need to be available. It is sometimes necessary for the auditor to discuss arrangements with the organisation before they can be finalised.

Formal communication is used to ensure no misunderstandings.

Selection of auditors.

It is important to select appropriate auditors for the audit to be undertaken. The team leader and Audit Management may jointly select the team required for a particular audit if this has not previously been undertaken by Audit Management.

The ability of team leaders and members to interface effectively with the auditees should also be considered.

The Corrective Action process

The audit has been completed once the auditors have conveyed the findings to the appropriate regulatory management function (verbally and in writing).

It is recommended that the audit life cycle is split into two separate processes. The audit itself and the corrective action phase.

IT IS A PRIME RESPONSIBILITY OF THE AUDITOR(S) TO COMPLETE THE AUDIT PROCESS AND PROVIDE MANAGEMENT WITH DETAILS OF THE FINDINGS

The Regulatory management function responsible for continued approval decisions is fully responsible for the determination and implementation of appropriate corrective action in a timely manner to ensure that system weaknesses are rectified as soon as practicable.

However, the regulators audit management function should be satisfied that corrective action proposed will deal with the root cause of the problem and when implemented is fully effective in eliminating the noncompliance found.

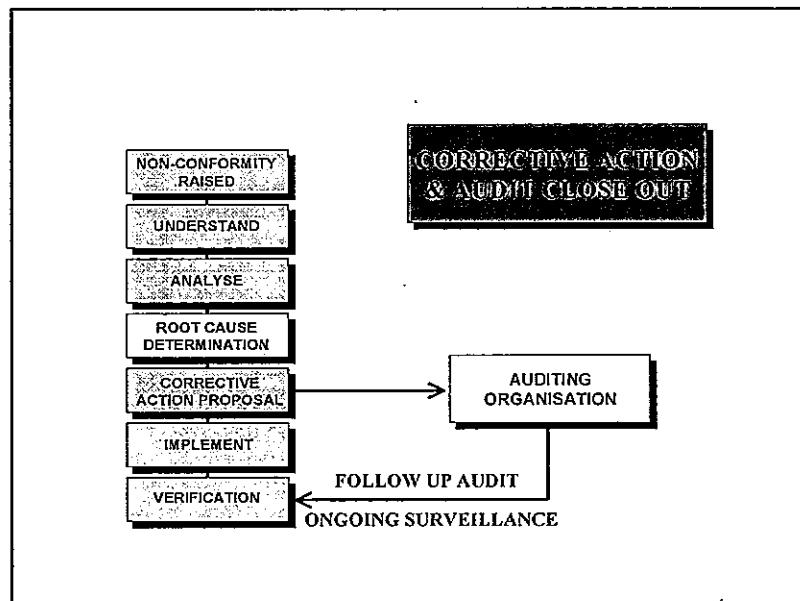
It is important to recognise that the audited organisations management are fully responsible for determining suitable corrective actions and appropriate timescales, however the regulatory organisation may need to define timescales based on safety regulatory concerns.

Should effective corrective action not be taken, or no indication given as to when it will be fully considered, then audit management must refer the matter to higher authorities once all other means of eliciting a suitable response have been exhausted. This may be when a regulator considers the need for enforcement action.

Once corrective action has been implemented then audit management should arrange for formal verification that it is effective in overcoming the original noncompliance. This may, or may not, involve the original audit team.

Audit Management need to be satisfied that the corrective action is taken and effective, this should be formally recorded (preferably on the original audit report form) and the audit 'closed out'. This check on the effectiveness of the corrective action is aimed at establishing that the root cause of the problem has been addressed and that the problem ('symptoms') found on the initial audit is no longer evident. This will require appropriate audit samples to check for the problem previously noted in appropriate areas of the organisation.

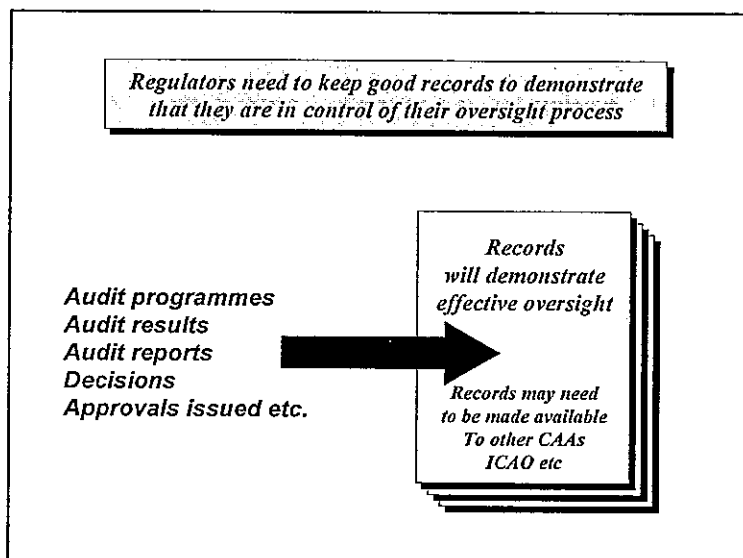
It may be useful to check the ongoing effectiveness of any corrective actions again at subsequent oversight audits.



Audit Records.

It is important for a regulatory organisation to keep good records of its regulatory oversight activities in order to be in a position to demonstrate the effectiveness of its oversight process. Such demonstration may need to be to international agencies such as ICAO, or in response to legal proceedings where a regulator will need to convince the legal process that the regulator has acted responsibly in relation to the implementation of oversight and response to findings.

Records will relate to oversight audit programmes, audit results, audit reports and the justification / reasons (rationale) for regulatory decisions.



A regulators audit / oversight records may be examined by external auditors such as ICAO USOAP (Universal Safety Oversight Audit Programme) audit teams.

The following should be considered for inclusion as part of the formal records of audits undertaken in an organisation:

AUDIT RECORDS

AUDIT IDENTIFICATION
AUDITOR DETAILS
PLANNING DATA
CHECKLISTS
AUDITOR NOTES
NONCOMPLIANCES
AUDIT REPORT
CORRECTIVE ACTION PROPOSALS
CORRECTIVE ACTION VERIFICATION

Remember, records are evidence of effective operation of the management system. We need to demonstrate that audits are effectively planned, undertaken and closed out. Audit management should determine what is to be retained as audit records.

In particular the regulator will need to demonstrate that its inspectors have taken appropriate audit samples and have applied a systematic approach to the undertaking of oversight visits. Audit records should indicate what has been examined during the audit and what was revealed.

Standardisation of Auditing.

It is necessary for regulatory organisations to ensure that auditing is undertaken by their inspectors in a common and consistent way across in relation to all regulatory oversight activities. This is necessary to ensure not only that the regulator obtains audit information in a consistent way and to the same level of detail from all inspectors, but it is very important to ensure that all regulated organisations are being treated fairly and consistently irrespective of their geographical location and the particular inspector visiting them. It is simply not acceptable for industry to see a change of inspector and a subsequent different level of auditing. There are commercial considerations linked to the activities of regulators, and an overzealous regulator can impose an unnecessary financial burden on an organisation by making excessive demands for corrective actions which are not resulting from noncompliance with regulations, but more associated with the particular regulator's personal agenda for how an organisation should be working. It must be recognised that regulated organisations only have to satisfy the regulations, they do not have to satisfy the requirements of individual auditors/inspectors.

It is necessary therefore for a regulatory organisation (particularly if it is large and operates from geographically separated offices), to ensure that all of its inspectors undertake audits in a common and consistent way. Clearly training will be an essential part of this process of harmonisation and standardisation, however training alone will not be sufficient.

It will be necessary to provide good guidance and supporting procedures for the regulatory auditing activities, it will also be necessary to see that the procedures and guidance are used. An internal auditing process should be put in place that will act to verify the use of necessary procedures and the adoption of good practices promoted by guidance material. The auditing process should not only verify that procedures are being used across the regulatory organisation in accordance with the procedures, but auditing should also verify the correct application of auditing techniques during the process of regulatory audit itself. Therefore there should be auditing of the auditors whilst they actually conduct their regulatory audits. This is likely to identify where further training and/or guidance or procedural detail might be necessary.

Additionally, harmonisation and standardisation of auditing can be facilitated by allowing different auditors to work with each other, by encouraging self development /improvement programmes, and by regulatory organisations to share each others auditors on regional cooperations (this routinely happens in the scandinavian countries for example where an oversight visit to an organisation in Norway might involve auditors from Denmark, Finland, Greenland, Iceland, or Sweden - this has been noted to be of real value to the regulatory organisations in these countries.

Applications of Auditing within Regulated Organisations.

Auditing is a very powerful tool that may be used by organisations to verify the application and effectiveness of their own management systems or the systems used by their suppliers and contractors. Regulatory Authorities need to understand where and how organisations might be using auditing techniques in support of regulatory compliance and will therefore need to establish that the process is working effectively.

Internal Auditing

Auditing undertaken by an organisation on itself is a very powerful and important feedback mechanism which provides both confidence to management and employees that all is going according to plan and also identifies opportunities for improvement. Internal auditing is a 'self monitoring' process. Such audits may be delegated to an external contractor, and may include:

Auditing of Quality or Safety Management Systems to verify implementation and effectiveness (in relation to Flight Operations, Flight Crew Licensing, Maintenance, Aerodrome operations, ATC, etc).

Auditing of general management systems to verify implementation and effectiveness.

Auditing of projects or programmes of work to verify conformity with Terms of reference, contracts, Quality Plans, etc.

Auditing of industrial processes to verify conformity with process specifications.

Auditing of key business processes and procedures to verify conformity with and adequacy of process descriptions and procedures.

Auditing of key documents, or process outputs to verify adequacy of processes used.

Auditing of products to establish confidence in production methods and quality control techniques employed.

Auditing of products to verify conformance to product standards.

Auditing of service provision to verify conformance to service standards.

Auditing of Suppliers and Contractors.

Auditing undertaken by an organisation upon its suppliers or contractors forms an important and integral part of a supplier management and development programme. Such audits can involve:

Audits of potential suppliers and contractors to establish confidence in their ability to meet the requirements of the purchasing organisation (can involve system, process and product audits as required), and to assist in the process of supplier selection and determination of supplier control mechanisms. (This type of audit is often termed "Supplier Evaluation").

Ongoing supplier performance monitoring - when the performance of the supplier is monitored against defined and agreed requirements such as a formal Service Level Agreement (SLA) detailing the exact performance standards to be met by the supplier. This may be undertaken continuously or from time to time as part of an auditing activity.

When supplier deficiencies become evident and it is considered necessary to undertake an audit to assist in the identification of weaknesses in the supplier organisation's management system.

Auditing of suppliers and contractors in order to identify opportunities for improvement in the supplier or contractor organisation management system - may be used as an integral part of a "Supplier Development" programme where an organisation wishes to develop the competence of a supplier and so better support the organisation.

Such audits may be delegated to a contracted auditing organisation.

Most airlines will use a wide range of suppliers and contractors to provide products and services in support of operations. It will be necessary to ensure that these organisations are both competent to perform the work and also that there is some form of ongoing monitoring of the work that they undertake in order to ensure that standards are maintained. This is recognised in EU OPS, and in the previous AMC to JAR OPS (Subpart B, AMC OPS 1.035) there was specific mention of the need for an operator to understand that the "ultimate responsibility for the product or service provided by the sub-contractor always remains with the operator" (*where the term 'sub-contractor' is understood to mean any organisation performing a major support function and for which the operator will have possibly put in place some formal arrangements such as a contract - normally termed 'contractors'*).

Auditing can have a very important part to play in our dealings with suppliers, contractors and sub-contractors and should be used by an organisation in a very pro-active manner to ensure that the performance of suppliers and subcontractors is always fully adequate to support operations and minimises the possibility of poor performance presenting any safety risk. Many major organisations use auditing to assist them in the selection and ongoing control of their suppliers in order to ensure that their own standards are maintained in a fully cost effective manner. Such auditing provides an important element of an overall comprehensive supplier management and development programme where organisations have recognised that poor supplier performance could in turn lead to increased costs and customer complaints.

In a very safety conscious industry the careful selection and ongoing monitoring of suppliers is an essential ingredient of the safety management programme. Supplier poor performance could in turn lead to safety related incidents, and it is no defence for an operator to simply claim that an incident was due to a supplier deficiency. Well managed organisations ensure that they use well managed suppliers, and any known weaknesses in the supply chain need to be rectified or mitigated through increased supervision or inspection of products and services.

The usual approach to supplier management is initially to select a supplier from a group of potential suppliers for the product or service in which we are interested, place our order and monitor the suppliers performance. However this is a very simple summation of what often turns out to be a very complex and often difficult process. Depending upon the nature and importance of the product or service that we wish to purchase so our approach needs to be modified accordingly. *(Supplier Management is the generic term given to the buying in of products and services. Supplier is the generic term given to suppliers and contractors)*

Initial selection of a supplier:

The following process is mostly used where there is a need to select a supplier of major services or where the quantity of supplied product results in very significant expenditure. Typically this process would be used for ground handling services, maintenance provision, wet leasing arrangements, catering supplies, training services, cabin refurbishment, procurement of in-flight entertainment systems, aircraft modifications etc.

The operator would short list possible supplier organisations, invite bids and obtain formal price quotations.

Technical evaluations would be performed by appropriate technical staff (or a contracted agency).

A financial status report would be obtained for each potential supplier.

Management systems evaluations would be performed by appropriate specialists.

One of the potential suppliers would then be selected following the comparison and evaluation of the above data inputs to arrive at a final decision on the price versus associated risks. The point of the exercise being to obtain the best value purchase where the contract price is fully considered in relation to the identified risks working on the principle that price alone should not be the overriding factor for reaching a purchasing decision (it has been noted that managers making purchasing decisions seem to want to obtain purchased products and services for the lowest price and yet when they choose their company cars they always seem to want to pay the highest price !!).

Effectively this process is a form of risk assessment activity, following which contracts and future monitoring/controlling actions may be determined to mitigate identified risks attached to using the chosen supplier.

There will always be trade offs, and inevitably there will be risks attached to using any supplier, however risks that are known may then be minimised through appropriate action, whereas risks that are not identified can eventually cause severe problems which at the least will be an inconvenience and result in additional cost, at the worst will result in an incident that could severely impact on the viability and survival of the operator.

Following the formal evaluation a contract and associated service level agreements may be put in place, which will incorporate any measures seen as necessary to overcome identified weaknesses, recognising that in some cases it may not be possible to obtain any supplier commitment to improve on current work processes due to the fact that they are the only choice (monopoly service provider at an airport) and can therefore get away with low standards of service. However in this case the operator may need to implement additional measures to safeguard against identified risks. For example, if it is noted that there is poor supervision of ground handling staff or poor security practices, then the operator will need to consider implementing additional supervision by its own staff or implementing additional security measures, all of which costs money !

Returning to the purpose of the formal evaluation, it may be seen that there will always be a trade off:

When using a supplier who presents a risk but who provides a low price quotation it may be the case that the cost of additional measures necessary to guard against noted shortcomings will result in the total cost being in excess of the price quotation of a supplier who presented lower risk in the first place.

There is a presumption that an "approved" organisation must be acceptable for use as a supplier. Unfortunately the regulator is only looking for regulatory compliance and an approval is issued on the basis of this. The regulator is not concerned about the overall efficiency of the organisation, nor does the regulator look at the more business related approaches to work process management. Therefore it is perfectly possible for an organisation to hold approval and yet their general approach to doing work is so poor that they are barely able to remain a viable business. This situation could certainly prevail in relation to airports and airport service providers where the airport remains effectively a quasi government run organisation with poor staff attitudes and generally very inefficient working practices.

Ongoing Supplier Audit

This is an activity that may be undertaken after a contract, or order, has been placed with a supplier either as the normal process of vendor performance monitoring or in response to a specific problem detected by the operator. Such auditing may be of the Systems, Product or Process type, and in some instances may involve a complete re-evaluation as per the original evaluation or supplier assessment process.

The level of auditing to be undertaken will be directly influenced by the results of the initial evaluation. If there are considered to be risks attached to using the supplier, then the level of auditing may be increased. The purpose of this auditing activity is to be satisfied with the continued ability of the supplier organisation to work in satisfaction of the contract and associated service level agreements.

Each audit undertaken will need to focus on specific requirements considered to be important to the operator.

Such auditing is now common place in relation to ground operations, and many operators routinely audit airport operations, where the audit is conducted on their own airport functions as well as the activities undertaken by handling agents etc. This of course has led to some airports being continuously audited by a constant stream of operators, all of which may have their own unique requirements. Unfortunately it is often the case that these requirements are not cascaded down to working level, with the consequence that whatever aircraft is being handled the staff actually performing the work will always do the job in the same way. This is a particular problem where there are language difficulties and the operator's auditors are unable to communicate with the staff or read and understand the translation of their organisation's requirements into local instructions. In these cases it will be necessary for the auditors to use local translators.

The Approval Audit Process

An overview of the process

Pre-Audit Visits

Document Review

Initial Preparation for on-site audit activities

Development of an Audit Visit Schedule

Communication

Detailed Audit Planning

The On-site Audit

Formal Reports

The Corrective Action Process

Follow-up and close out of corrective actions

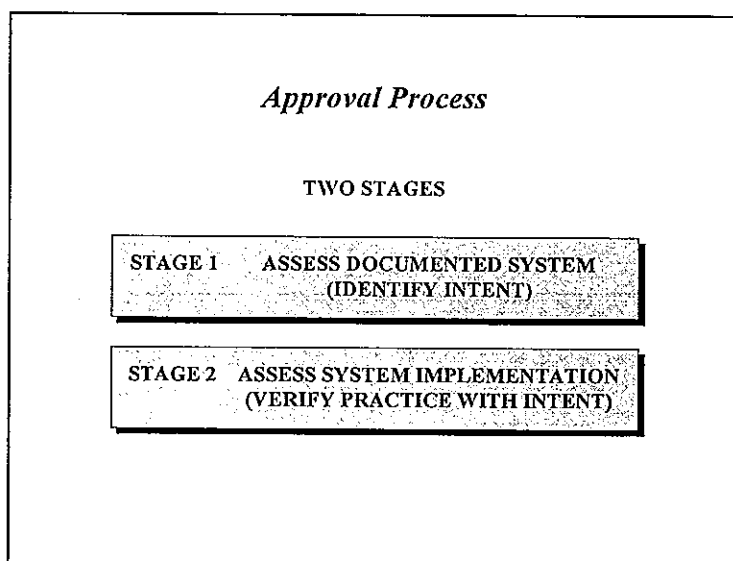
An Overview of the Process.

An Initial Oversight of an organisation, conducted as part of an overall Approval or Certification activity involves two separate stages:

- Stage 1: A review of the documentary evidence provided by the organisation to demonstrate that it has adequately addressed the appropriate requirements in its documented system. This is sometimes referred to as a "Desk Top Audit", however it is not an audit at all but a full and formal review against a full set of requirements that the organisation is required to meet.

- Stage 2: An on-site audit to establish that the organisation is indeed implementing it's documented system. This is a true audit that involves sampling of activities undertaken or records relating thereto.

The need for undertaking this process will be in response to an organisations request for approval and the regulatory organisation will need to identify a person within its organisation who will have the responsibility for managing the process on behalf of the regulator. This person will need to plan for the conduct of the two stages and arrange for the necessary resource to undertake the document review, conduct the audit and provide a formal report to the regulatory function responsible for granting the Approval/Certification. This person is likely to be identified as the Team Leader for the process, even if there is only a team of one !.



Although there may be variations in the way that individual organisations carry out audits there are some generally accepted protocols and elements of good practice that have evolved and are now accepted as "best practice" and incorporated into ISO 19011. In the following pages what has generally come to be regarded as the standard approach to carrying out an Approval/Initial Oversight will be detailed and is believed to be a desirable approach to encourage.

The general process involves the following activities:

DOCUMENT REVIEW

PREPARATION FOR AUDIT

Initial Preparation
Development of Audit Visit Schedule
Communication

DETAILED AUDIT PLANNING

THE ON SITE AUDIT

Opening Meeting
Audit
Evaluate Results
Closing Meeting

FORMAL REPORT

Each of these will be examined in turn.

Note: In advance of an audit it may be necessary to undertake a "Pre-Audit Visit" in order to clarify the process with the organisation to be audited and/or as a means of enabling the audit team leader to obtain the necessary understanding of the organisation to facilitate the audit visit planning. However this should not be used as a means of undertaking auditing.

There is also the possibility that following the audit the regulatory organisation may require action to be taken by the audited organisation in response to audit findings. This may in turn lead to a formal audit follow up and verification of the effectiveness of corrective action taken by the regulatory organisation which may or may not involve the auditors who performed the initial approval audit.

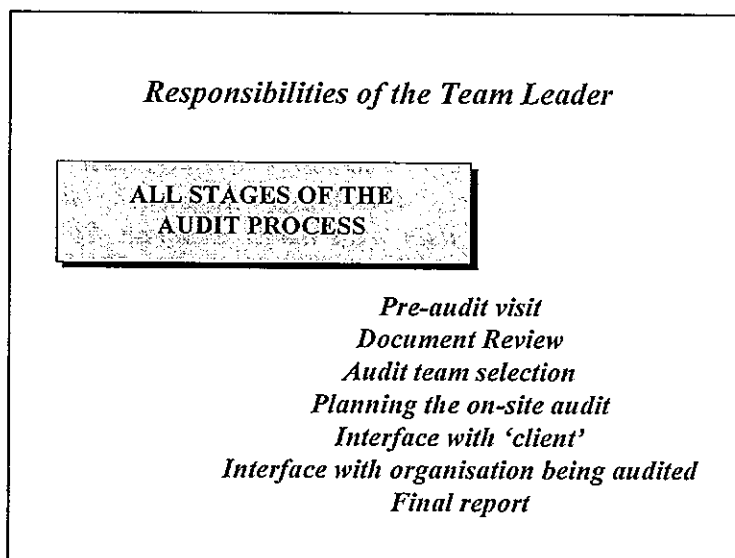
Responsibilities in relation to the Audit process

Whether an audit is to be undertaken by a team of several auditors, a Team Leader should be nominated to act in an overall managerial capacity to ensure that required objectives are met and the audit is undertaken in a professional and fully acceptable manner. The necessity for a team of auditors to undertake the on-site audit will vary depending upon the magnitude and complexity of the task, in some cases technical experts may also need to be included to work with and assist the auditors, or auditors with certain specialist knowledge.

Generally all auditors are responsible for:

- Conformance with audit objectives and scope
- Planning for individual audit assignments
- Carrying out individual assignments efficiently & effectively
- Documenting and communicating findings
- Respecting confidentiality
- Remaining objective
- Cooperating with and supporting the Team Leader

The Team Leader has some additional responsibilities in relation to the entire audit process. In particular acting as the prime interface between the organisation requesting the audit (client) and the audit team, and also between the audit team and the organisation to be audited. The Team Leader will be expected to chair key meetings such as the Opening and Closing meetings, and will possibly be the only member of the team involved in any pre-audit visits.



Initial contact.

For Regulatory audits the initial contact could be either at the request of the organisation or the Regulatory Authority.

For any audit that is to involve a formal on-site audit initial contact will be used to:

- establish communication channels,
- confirm authority to conduct audit,
- provide information on proposed timing and audit team composition
- request access to relevant documents,
- determine applicable safety rules,
- make general arrangements for the audit,
- agree on the attendance of observers and the need for audit guides.

It is normal practice for the Audit Team Leader, or person responsible for the audit function within the auditing organisation to undertake this initial contact and to ensure adequate communication of the purpose of the audit.

Approval Audit Process

***There needs to be a clear understanding
between the auditing organisation
and the organisation to be audited;***

***WHY it is necessary, and
WHAT WILL HAPPEN
when the result is known***

Pre-Audit Visits.

The purpose of a pre-audit visit is to ensure that both parties understand the objectives and scope of the audit, to ensure that the organisation to be audited has a clear understanding of what the audit is all about and what it will involve, and to enable the auditing organisation to gather preliminary information about the target company and to communicate clearly its reasons for wanting to carry out an audit and how the audit will be undertaken.

It is usual to request some data at the pre-audit meeting such as:

- Nature of business
- Product / services
- Company details (employees, turnover etc.)
- General organisation
- Outline of Management System (in the form of a Manual / Exposition).

It is essential to obtain sufficient information to be able to advise the company if an assessable Situation exists and to enable "Document Review" to be undertaken.

At, or shortly after the pre-audit visit agreement should be reached as to how the Regulations are applicable to the company/s operations, and in particular the **Scope** of the audit. Scope relates to the geographical areas of the organisation, or specific company operations / product activities that are to be the subject of audit activity.

It is normal practice for a pre-audit meeting to be arranged and undertaken by the Team Leader (or person responsible for managing audit activity) The meeting should last only two hours maximum, and may also involve a brief walk around the organisation. Information obtained at a pre-audit visit will assist in the preparation and planning of the on-site audit.

Document Review.

The purpose of a document review is to clearly establish if the organisation's documented system adequately addresses the necessary Regulations and communicates the company's policies, organisation and responsibilities in relation to them. Also to establish if sufficient controls (procedures) exist in relation to all activities undertaken by the company. This also forms part of the process of determining if an auditable situation exists and if it is appropriate to go ahead with an audit. It is at this stage that the Team Leader will decide whether to continue with the audit process or indicate to the company that there remains some further work to be done.

A document review is usually undertaken on the organisation's Manuals/Expositions (or equivalent) together with listings of company procedures. It is not normally necessary to request other documents, however sometimes it may be necessary to look at one or two procedures to ascertain if they generally look acceptable for the purpose of communication and control. However it is not the task of the auditors to criticise the general format and layout of such documents, nor to require vast amounts of detail explaining exactly how tasks are undertaken, remembering that the detail required in procedures is dependent upon the training and expertise of those for whom they have been written.

The results of a document review should be communicated back to the organisation as soon as possible, comments should be restricted to main concerns only AND NOT TRIVIA such as layout, format, spelling etc.

It is usual for Manuals / Expositions to closely follow the main headings of the appropriate Regulations, however there is no mandatory requirement to do so and authors are free to choose any style or format they wish. The assessor should not demand that a Manual / Exposition be written in any specific way and should always remember that the Manual / Exposition exists to enable the company to implement its own Management System. Subjects additional to Regulations headings may be present, and there is nothing wrong in that (it is to be encouraged!). In the case of the need to meet regulatory requirements it may be necessary for the Manual to comply with defined criteria and in this case the document review will be carried out against those criteria.

Modern approaches encourage a more common sense approach with the necessity for procedures and the associated level of detail being balanced against the need for control and the skills and abilities of those who need to use the procedures. Clearly, for highly competent and motivated individuals procedural detail may be largely irrelevant and unnecessary, particularly when engaged in fairly standard and repetitive tasks. However, for individuals who are not so skilled and experienced, or where there is high staff turnover then a greater level of procedural detail in an organisation may be very necessary. It is not for auditors to determine the level of procedural detail necessary in an organisation, but to clearly establish if this has been given due consideration and acted upon accordingly.

Auditors will need to look for clear signs that the level of procedural detail is sufficient to ensure satisfactory outputs from work activities. It is particularly important to recognise this changed emphasis on documentation in the early stages of audit planning, and in particular when undertaking a "Document Review" of an organisations quality management system. The auditor will need to clearly establish that the organisation has carefully thought about the high level documentation that is required in the form of Policy, Objectives, Manual / Exposition, Plans etc. together with the procedures necessary to exercise appropriate control over those processes considered to be fundamental to the organisation's operations. In most organisations there will be a collection of main or 'key' business processes which will require formal control together with a number of support processes and general disciplines relating to many of the activities undertaken throughout the organisation.

During such documentation reviews the auditor will need to develop a good understanding of the nature of the organisation's activities and will clearly need to understand which are the main processes that should be the focus of audit attention. It will be necessary to establish how various processes relate to each other (this should be facilitated by the descriptions provided in the Manual / Exposition. It is necessary for organisations and auditors to understand much more about how an organisation actually functions and how various operations and activities combine to provide the full range of outputs.

All organisations are fairly complex, and there are a broad range of activities that are undertaken, all of which need to work in combination and harmony for the organisation to function effectively and efficiently.

The Audit Team Leader will often undertake the document review and may be assisted by other Audit Team Members if they are known and available at the time, and occasionally by a technical expert (in the case of Software etc.).

Initial preparation for on-site Audit activities.

It will be necessary for the team leader to develop an understanding of the company to be audited, its products, processes and organisation, to finalise the **Scope** of the audit, decide on the composition of the audit team and the outline on-site audit visit schedule and to begin the preliminary activity of developing a plan of action for undertaking the on-site audit.

It is important that before this preparation is undertaken the full objectives of the audit are fully understood by the team leader, and if there is any doubt then further discussion should take place with the organisation to be audited, or the client organisation requiring the audit. The scope of the on-site audit will now be finalised by the team leader, if necessary consulting with the client (person requesting the audit) or the organisation to be audited as appropriate. (The term "**Scope**" is used to mean those aspects of the company operations that are to be subject to audit, i.e. specific processes, departments or functional areas). The scope is determined by relating the company operations to the audit objectives. Thus if the audit is for an initial approval then the scope of the on-site audit will include all areas of the organisation that are involved with the provision of the organisation's product/ service having an impact of safety of operations. If it is some form of on-going oversight then the audit scope may be restricted to some areas only.

Scope of Audit

*Those parts of the organisation that
are the focus of the audit
and will be subject to audit activity*

*Determined by the objectives
and "client" needs*

It is at this stage that the team leader, or lead auditor, will decide on who from the available pool of auditors would be best to include in the team, either due to knowledge and experience with this particular industry or because a specific technology undertaken by the Company requires the audit team to be accompanied by an appropriate technical expert. An audit team may include a technical expert who is only involved in assisting an auditor and not actually auditing, and occasionally an auditor with specialist technical knowledge may only be involved in undertaking a small proportion of the audit and hence is only present for part of the time (this can cause problems if such an expert is not available for the Closing Meeting, when nonconformities involving technical matters may need to be discussed, and it should be so arranged that all members of the audit team are available for the Closing Meeting even if they were not all available at the Opening Meeting).

The team leader will undertake this preparation by studying documents and data obtained at the pre-audit visit, talking to others who have some knowledge of the business and/or technologies involved, or referring to other information.

The question often arises, "how many auditors will be required and for how long". This is almost the same as "how long is a piece of string". Judgement is required based on practical experience of auditing and the nature of the different company operations. Auditors with greater experience are likely to require less time than less experienced auditors to gain the same confidence in an organisation. It also depends on the "sample" that is to be taken (activities to be audited and requirements that they will be audited against). The Team Leader may wish to develop a better understanding of the company by undertaking a form of **Process Analysis**, which will also assist in determining a suitable audit sample.

General Guidance

More time will be required in larger companies. More time will be required when complex technologies or business processes are involved. Two auditors can cover more ground and in greater depth than one (not necessarily twice as much!), and the involvement of more than one auditor allows for comparison of observations and active discussion on the direction that the audit should take, or trails that should be followed after the discovery of nonconformities.

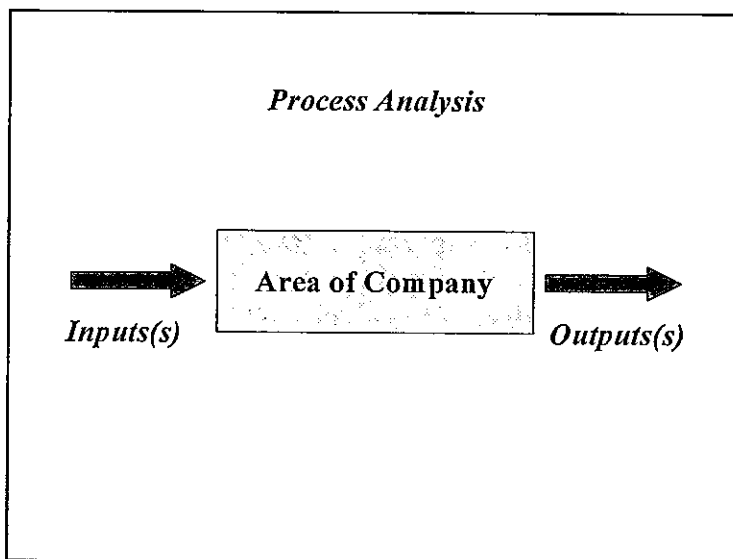
A typical company involved in medium technology design and manufacture operating on a single site with approximately 400 employees might require a team of three auditors for three days (i.e. 9 auditor days). A typical office undertaking sales and marketing activities with approximately 50 employees might require a single auditor for 1 to 1½ days. It should also be recognised that the longer the duration of the audit, the more disruption to the company, and efforts should be made to reach an acceptable compromise between the number of auditors and the total number of days over which the audit is undertaken. It may also be necessary at this stage to determine which specific requirements of a code/system standard must be verified as this will also have an impact on the audit duration. (See also section on "DETAILED PLANNING"). Accreditation Bodies usually issue guidance to Third Party organisations.

The Team Leader will need to undertake a detailed analysis of the organisation to clearly understand what is happening, where it happens, when and how. This can be achieved by closely studying company documentation such as organisation charts, Manual/Expositions etc. and by producing block diagrams of the company structure, flow charts showing how the work is progressed through the company structure, and by making educated guesses as to what should happen and roughly how. Process Analysis is a useful technique to assist with this process. Once this has been done it is then possible to clearly identify which of the requirements of the regulations are applicable in each section of the company. i.e. The audit "criteria" that are applicable.

Understanding the Process.

Initially auditors must develop a good understanding of the processes involved, and process analysis may assist in this task.

For the area(s) of the company that are to be the subject of audit activity the auditor must first develop a good understanding of what activities are undertaken, how and in what order. This process may be assisted by use of a process modelling / process analysis. Once this has been done it is then a relatively straightforward task to identify which of the management criteria have some scope for application in relation to the different activities.



We are now in a position to decide which of the requirements of a Management System (regulations) are applicable within this area of the company.

If each department within an organisation is identified by a unique number, then it is possible to 'map' the requirements of the management criteria onto the total company and display such on a Matrix chart. Such a chart may then be used for audit sample planning purposes, and to assist in the determination of times required to be spent in each department (or functional area) in order to satisfy that sample. An example of such a matrix chart, using a typical set of requirements is given below.

Clearly for some of the departments there will only be limited scope for application of the criteria, and so sometimes it may be of help to indicate the degree of relationship that exists between the individual criteria and the department that is to be audited (A, B, C, etc.)

Management System Matrix Chart

<i>Management System Requirements</i>	<i>Departments / Functional Areas</i>													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Clauses & sub clauses of the Regulation(s)														
1.0														
1.1														
1.2														
1.3														
1.4														
Etc.														
<i>Relationship between Management System and Departments / Functional areas</i>														

If such an analysis is carried out for an entire company operation the matrix chart would show how the management criteria related to all company departments or operations. However it would be impractical to undertake an audit to establish if all such criteria requirements were indeed being met in each of the company departments as such an audit would require a very large amount of time. We need to recognise that auditing is always undertaken on a sampling basis, and thus it is only necessary to select a realistic and practical sample of criteria in some departments only.

It is at this stage that the auditor needs to refer to the original audit objectives and to select an appropriate sample. This sample must be determined such that it will provide sufficient confidence that key criteria are indeed being implemented within the organisation. If an auditing organisation undertakes over a period of time a series of surveillance audits, such as might be the case for Regulatory Authorities, then such sampling may be used to very good effect to establish if all criteria are being complied with. Each audit will focus on certain selected criteria only and also be restricted to some of the organisation's operations. However, for each audit a different sample will be taken such that over the selected period of time all criteria will be sampled in all of the organisation's operations. Clearly for this approach to be fully effective it will be necessary for records of each audit sample to be maintained and for each auditor to consult such. Audit Management will need to steer this process to ensure that suitable samples are taken at each audit to provide for satisfactory audit coverage.

Development of an Audit Visit schedule.

It will be necessary to clearly detail which aspects of the company operations are to be subject to audit/audit activity, for how long and by whom, and also to indicate to the organisation to be audited which members of staff will be required to be available for interview by the auditors.

Although there are some general guidelines issued by Third Party organisations and their controlling authorities, it is not always easy to decide the exact audit timings and resource levels. This can be very dependent upon many different factors, not least of which is the relative knowledge and experience of the auditors themselves (particularly with respect to the organisation to be audited). In some cases educated and experienced judgements are required.

Basically it is necessary to judge how long needs to be spent in the various areas of an organisation in order to obtain a reasonable degree of confidence in the organisation's ability to meet the appropriate specified requirements. Larger and more complex situations will require more time, as will geographically distant and spread out locations. Time constraints together with resource and cost limitations may also influence the final audit visit schedule. The relative responsibilities of the team members should be agreed and detailed in writing. Technical experts may be required to assist the auditors where particular technical subjects need to be audited.

It is at this stage that the Team Leader will need to finally decide the criteria (requirements) that will need to be verified in each area of the organisation in order to ensure adequate coverage, and to gain sufficient confidence in the organisation's compliance with the regulatory requirements. (Clearly if this is left to the individual auditors to determine for their own audit areas then certain requirements may not be verified). It is often useful to use some form of 'Matrix Chart' to summarise the results of this planning activity.

In many cases an auditing organisation will need to determine if key processes are being implemented effectively in an organisation. In particular, where key processes are implemented across several departments (cross functional processes) audit planning will need to identify which key processes are to be verified by audit, and a conscious decision taken to either arrange for the audit to be focused on individual departments or to 'follow' processes across the organisation. In the event that cross functional processes are to be verified the team leader will need to devise an audit visit schedule that will ensure audit activities are undertaken in the relevant departments and in an appropriate sequence, together with appropriate samples for the team members.

It is now possible to break the audit down into manageable portions, allocated to each auditor in the team and thus produce a suitable audit/audit visit schedule.

The team leader must ensure that the audit visit schedule clearly indicates who will be where and at what times.

Several different styles of audit visit schedule have been observed, however the one that is recommended is as shown below, and clearly details the various audit tasks that are to be undertaken by the team members. It can also be used to show the criteria that are to be verified in each audit target area.

The Audit Visit Schedule is, in practice, detailing a series of individual audits that are to be undertaken by the team members throughout the duration of the on-site audit. It should also be noted that until this schedule is accepted by the organisation to be audited it remains only a proposal.

In summary, The team leader will plan the audit by studying documents such as organisation charts, Manual/Expositions etc., and by discussing with other team members. Also by gaining information at pre-audit visits and by **using the technique of Process Analysis**. The Team Leader should agree and finalise the proposed schedule, working where possible with the audit team members, and it is then his/her job to agree the proposed audit visit schedule with the organisation to be audited.

Communication.

It is very necessary for the team leader to ensure that there is a clear understanding at all times of the proposed audit arrangements between the Audit Team and the organisation to be audited. Particularly in relation to the audit visit schedule and key staff that will need to be available, support requirements (office facilities, guides, the need for protective clothing, etc.), and the suggested attendees for Opening and Closing Meetings.

In relation to support requirements, the team leader should determine what will be required to support the audit process, such as office facilities etc. It is normal practice for the team leader to request the use of an area where the audit team may be based and where they may be able to meet for private discussion, and to have access to any phone, internet access or secretarial support as necessary. The team leader should also establish if there are facilities for taking lunch.

It is important to note that at all times the team leader should remember that requests may be made, but that it is wrong to make demands !

It would also be appropriate for the Team Leader to check at this stage on the working times, lunch times and any restrictions on access that there may be due to safety hazards, confidential processes etc., and to request that "Guides" be provided to accompany the auditors during audit conduct. The role of the guides, and hence their level of knowledge, seniority etc. should be explained to the company.

As part of the communication process it is also advisable to telephone or email the company a week before the audit, just to ensure that there have been no misunderstandings and that the company is fully prepared and made all the necessary arrangements. (Remember, with email it is necessary to ensure that a reply is received to be certain that the communication has been received and understood.)

The team leader should communicate the PROPOSED audit visit schedule, date for audit and any support requirements by formal letter to the auditee organisation. It is a primary responsibility of the team leader to ensure adequacy of communication throughout the complete audit process.

Detailed Audit Planning.

The Audit Team will need to be adequately prepared for the audit, have a good understanding of the company, the nature of its business, its products, the technologies and/or processes involved and most of all they know what to look for and where to look to verify conformance to the Regulatory requirements. The Team also should know fully who is to do what and when and how they will handle the evaluation of data.

The Team Leader will need to communicate to the audit team the schedule and audit criteria to be checked (sample), and the audit team members will need to closely study company documentation such as organisation charts, Manual / Expositions etc. and where necessary use process analysis to ensure a sufficient understanding of the activities undertaken and how the requirements that they are auditing against relate to those activities.

Each of the auditors will need to undertake his/her own detailed planning involving the development of their own working documents in the form of:

- “High level” check lists
- A personal plan of action (auditor's strategy)
- Low Level check lists.

The On-site Audit.

The on-site audit will involve the following:

An Audit Opening Meeting,
The Audit,
Evaluation of the audit findings,
An Audit Closing Meeting.

The Opening Meeting

Following arrival at the organisation the Team Leader should hold an opening meeting with the company management team or representatives thereof. It must be remembered that from now on the auditors are guests in the company, and as good guests they must always be on best behaviour. They must not demand, only request. They may wish to hold meetings with company management but they do not have the right to demand this or even attendance at any meeting by any one member of the management team. However, when making such requests they should carefully note the response and willingness on the part of the company to co-operate and meet such requests.

The purpose of the Opening Meeting is to introduce the Audit Team to company management and allow management to do likewise. Also to re-state the purpose of the audit i.e. the objective and scope, how it will be undertaken and how the results are to be communicated back to the company. It should be made quite clear at this point if immediate feedback of observations/findings/noncompliances will be provided using a custom designed form, and how this is to be handled. Also the company should know if a daily closing meeting will be held for a summary of the days findings, or if all findings will be left for the final "Closing" meeting. (Preferable to leave until closing meeting).

It should be stated that the audit is only a limited 'sample' and conclusions reached at the end of the audit can only be based on what is revealed by the sample taken by the auditors. This is a 'snapshot' at this moment in time.

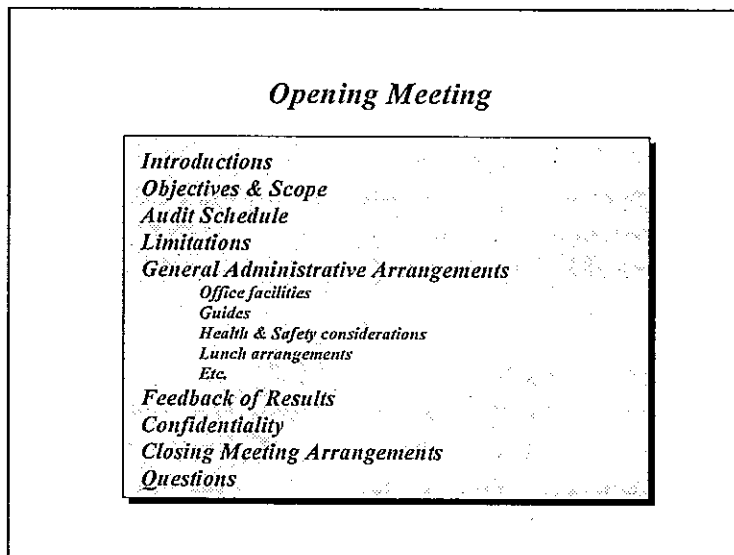
General administrative arrangements, such as office facilities, breaks, starting and finishing times should be addressed. It should also be established if the previously supplied schedule is still acceptable and if there are any reasons for making adjustments to this. Also will guides be available. Company starting and finishing times should be re-checked together with possible staff/union difficulties etc.

The team leader should also ask if there are any Health & Safety requirements or considerations that the audit team need to be aware of (safety hazards in the areas to be audited etc.).

Arrangements for final feedback of results at a formal "Closing" meeting should be discussed (time, duration, who should be present etc.). If a report is to be produced it should be stated when this will be provided.

It should also be made clear to the company that everything seen and heard by the auditors, and results obtained will be in total confidence and will not be revealed to any other parties.

Finally, allow a period of time for questions from company managers. We want them to feel comfortable with the process.



Audit Conduct

This should be conducted in accordance with the laid down schedule, keeping to the set times as far as possible and following each auditor's detailed plan. Remember that the purpose now is to get on with the job and answer **ALL** the questions on the High Level Check List.

It is normal practice to request auditee organisation staff to accompany individual auditors in the role of 'guides', not only to show the auditors where to go but to introduce them to interviewees and, most importantly to act as witness to facts found that relate to nonconformities.

As non-conformances are found they should be clearly recorded in a formal manner and company agreement sought that the facts surrounding/relating to the non-conformance are true and accurate. Nonconformities should be written onto official report forms as soon as possible following their discovery, and it is normal practice for auditors to do this either at the time the nonconformity is found or before leaving the area being audited. If they are not written down immediately then good notes will need to be taken. The guide will often be expected to enter his/her name onto the formal nonconformity report form to indicate concurrence with the observed facts, a practice that prevents possible problems later if the facts should be challenged!

As the audit progresses we may find that trails require to be followed which could detract from the individual auditor's plan, or even major concerns that need to be followed up and so result in a major change to the original audit visit schedule. How should these situations be handled and controlled?

It is a prime responsibility of the Team Leader to ensure that the audit is satisfactorily completed, having covered all areas originally decided upon and checked all appropriate Management System requirements.

Individual auditors are required to refer decisions to deviate from the agreed schedule to the Team Leader, and usually these matters are dealt with at regular team meetings held several times throughout the audit.

Team meetings may be held at coffee or lunch breaks and are an opportunity for the team members to exchange information, particularly relating to trails that may need to be followed by other team members. If a significant change to the schedule is deemed necessary by the team leader this should always be discussed and agreed with auditee management.

At the conclusion of each day it has become normal for the team leader to provide an overview of findings to the company's Management Representative (Quality Manager).

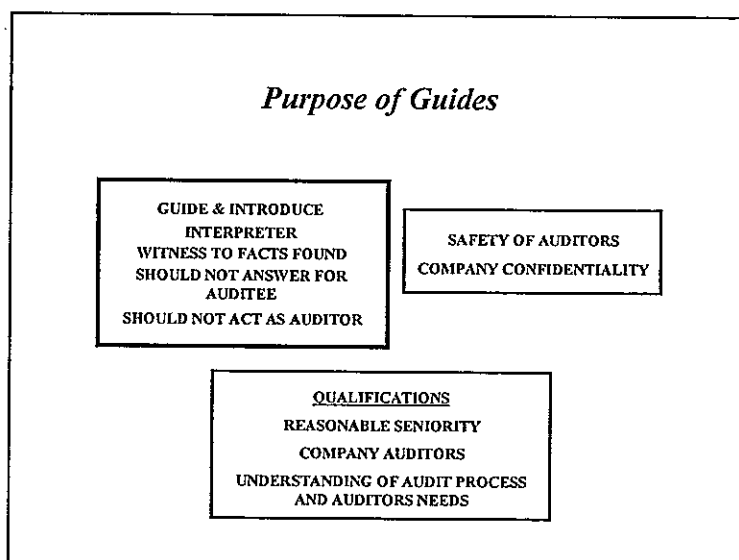
It is most important that the true role of such guides is fully understood by both the auditors, the auditees and the guides themselves. Guides are not there to act as a buffer between the auditors and the auditees, they should not themselves be audited, nor should they cut across the auditor or auditee by asking or responding to audit questions.

They are there to ensure that the auditors are able to move around freely in the company, are accompanied at all times to meet with company confidentiality and Health & safety requirements, and to ensure that fair play prevails.

In this latter respect, it is sometimes the case that either the auditor or the auditee misunderstands what is being said and in this case the guide can be valuable to see that such misunderstandings do not occur. The guide must also sometimes act in the capacity of Interpreter, not only from the foreign language aspect, but also to interpret company or technical terminology for the auditors.

As the guides can have such a significant and important role it is well to select them with care and choose suitable staff for this function. Inevitably a company will choose guides from its own QA staff.

The audit team leader should ensure that the guides allocated are suitable from the point of seniority, general abilities etc. and should politely request alternatives if inappropriate guides are allocated. The Team Leader should also be prepared to take action if guides should not act in an appropriate manner, and where necessary request alternatives.



Audit Team Meeting.

The audit team should meet at appropriate times throughout the audit process in order to share and exchange information and to determine if any audit trails need to be followed, changes to the audit plan are necessary and to generally check achieved progress against the required audit objectives.

Before the closing meeting it is normal for the Team Leader to arrange for a team meeting at which **only** the audit team are present. The purpose of this meeting is to evaluate all results and prepare a summary of findings which will be presented to the company at the Closing Meeting. It is important when reviewing non-conformances to ensure that the statements made are factual, supported by objective evidence and are clear, concise and understandable. If there is any doubt as to the ability to support a conclusion made then the non-conformity should be discarded.

Sufficient time should be allowed for this final team meeting in order to enable the team leader to prepare for the Closing Meeting. The Team Leader will need to chair and control this meeting.

Team Meeting

CHAired BY TEAM LEADER
NONCONFORMITY FORMS COMPLETED
ALL NON-CONFORMITIES REVIEWED

COLLECTIVE REVIEW OF NONCONFORMITIES
TO IDENTIFY MAJOR CONCERNS

SUMMARY STATEMENT PREPARED
AGENDA FOR CLOSING MEETING PREPARED

It may be possible to group some findings together, if they are clearly the same problem, and detail on a single non-conformance report.

In preparing the summary statement the Team Leader must return to the reason for undertaking the audit in the first place:

Does the documented system address the requirements of the regulation(s) and to what extent? (Are there weaknesses in relation to specific requirements or in relation to particular company activities?)

Is this system implemented and to what extent? (Again are there weaknesses in relation to specific requirements or particular company activities?)

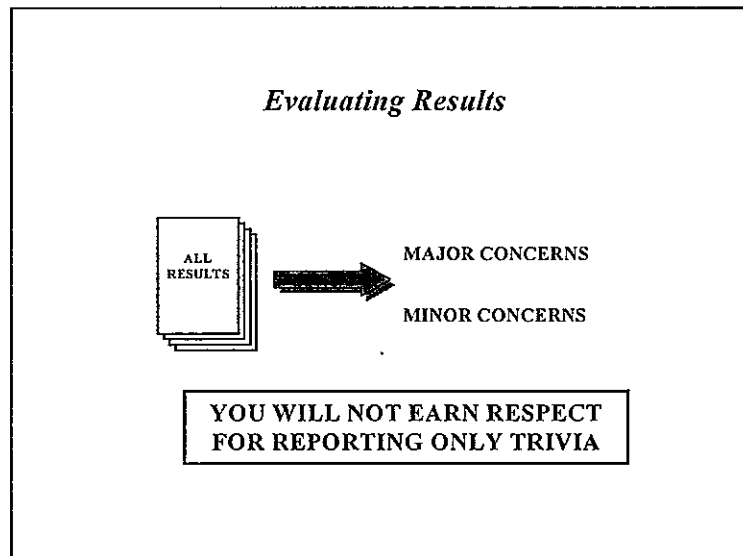
Is the system effective?

By analysing collectively the non-conformances raised the Team Leader will be able to answer these questions and make a meaningful input to the closing meeting by indicating areas of the company that are weak in these respects, and pass a final judgement on compliance to the requirements of the code/standard. Hence the conclusion of the audit team.

The agenda for the closing meeting will allow for presentation of individual findings by the team members if this is considered appropriate by the team leader.

Evaluating Results

As the auditors reveal non-conformances or make observation/findings etc. So eventually there will be a list of such. This list may be long or short, however some of the findings may be more significant than others, some may be closely related or manifestations of the same problem. The Audit Team will need to evaluate all of the audit results to identify any major concerns revealed by the audit.



Remember, management are not interested in trivia, they need to know what the main problems are. This evaluation may be undertake on a daily basis or at the end of the audit and before the closing meeting. It should be performed by the Team Leader with the Audit Team.

Some organisations categorise nonconformities as major or minor or attach a numerical indicator of severity i.e. Category 1,2 or 3. Although there are no formal definitions as such in any international standard the following are the generally understood definitions used by many audit authorities:

Major Nonconformity

A SIGNIFICANT NONCONFORMITY WITH A MANAGEMENT
SYSTEM REQUIREMENT

OR

A FAILURE OF, OR COMPLETE OMISSION OF A MANAGEMENT
SYSTEM REQUIREMENT

OR

A SIGNIFICANT NUMBER OF MINOR NONCONFORMITIES
CONCERNING THE SAME MANAGEMENT SYSTEM
REQUIREMENT

It is important for an auditor to differentiate between things that are of a serious nature and those that may be less so, however the above definitions in common use are considered to be somewhat subjective and could result in much debate at the time of audit, particularly if to receive a 'major' nonconformity could result in the lack of formal approval or loss of an order.

In some instances an auditor may be given information or make an observation that whilst not a non-conformance as such, indicates that potentially one might arise if the situation were not addressed. Auditors often use the category "Observation" for such instances, however it is felt that unless hard factual (objective) evidence of nonconformity is found by the auditor then one does not exist. The term 'observation' should not be used to describe a lower category of nonconformity.

EASA
Part 145.A.95 Findings

A level 1 finding is any significant non-compliance with Part-145 requirements which lowers the safety standard and hazards seriously the flight safety.

A level 2 finding is any non-compliance with the Part-145 requirements which could lower the safety standard and possibly hazard the flight safety.

No level 3, No Observations.

EASA
Part M Subpart I

A level 1 finding is any significant non-compliance with Part M requirements which lowers the safety standard and hazards seriously the flight safety.

A level 2 finding is any non-compliance with the Part M requirements which could lower the safety standard and possibly hazard the flight safety.

No level 3, No Observations.

The Closing Meeting.

The purpose of the Closing Meeting is to continue the communication process with the audited company's management team and to feedback the results of the audit, together with any conclusions reached, to ensure that company management are aware of and fully understand the findings and associated implications, and what they need to do next. Also to formally close the audit.

In a similar style to the opening meeting, the Team Leader should call (advised at the opening meeting) and chair a formal closing meeting (sometimes termed EXIT meeting) with company management. Again it must be remembered that you cannot demand attendance at such a meeting of management, however it is likely that they would not wish to miss such a meeting!

Again, it is wise to introduce Team Members to the management team, and allow them to do likewise and then spend a few minutes explaining the purpose of the meeting (there may be attendees who were not present at the Opening Meeting).

Before passing on to the results themselves the Team Leader would be wise to first thank the company for its co-operation, hospitality, provision of facilities, and the courteous and professional manner in which it participated in the audit process (even if it didn't!) Generally let them know what a pleasure it was to be in their company before letting them have the results.

It is recommended that the objective and scope of the audit be re-stated, for the benefit of any participants who may not have been at the Opening Meeting, and that the audit can only be a sample of the activities undertaken by the company and hence not every non-conformity that exists may have been found. The method of formally reporting the audit results back to the company should also be explained.

The audit findings should then be presented, usually by each of the team members in turn. Copies of such may be supplied to save the organisation's management needing to take notes.

Finally the Team Leader should present the summary and make the final conclusions clear.

Dependent upon the nature of the audit findings there may be some discussion on corrective actions, however it is unreasonable to expect well thought out and appropriate corrective actions to be decided at the closing meeting and the Team Leader should try not to become involved in a debate on individual noncompliances but leave copies of these with company management and obtain a commitment from them to provide a formal response by an agreed date (if the audit team leader is required to do this within the regulatory organisations procedures).

Closing Meeting

Introductions
Record of attendees
Purpose of meeting
Thanks for cooperation etc.
Restate Objectives & Scope
Limitations of the audit
Report
Summary Statement
Nonconformance reports
Corrective action & follow up mechanism
Questions

The results should be presented first in a summarised form by the Team Leader, and then in more detail by the individual Team Members for their respective audit areas. Clearly showing management what facts lead to the conclusions. You must be prepared to field detailed questioning at this stage and must decide whether to take questions as they arise or at the end of each auditor's presentation or at the end of the complete results feedback.

Presentation of the results may be assisted by the handing out of copies of audit report forms and/or the use of overhead slides.

At the end of the presentation copies of the audit results should be made available to company management.

Auditors should never leave an organisation without providing the details of all audit findings in a written form. This is to guard against possible future disputes.

Corrective Actions

Depending upon the nature of the audit undertaken, i.e. Initial Approval, ongoing oversight etc. it may be appropriate to discuss a timescale for the company to propose necessary corrective actions, however it should be remembered that this is a process that the regulatory organisation needs to exercise control over and it should not be left to individual auditors to determine this alone. It is often not possible, and even inadvisable, for corrective action to be determined at the time of the audit. Management need time to undertake the necessary investigations.

Auditors should not force the company to decide during the closing meeting what corrective actions are to be taken.

The Team Leader should indicate before leaving the organisation when the report from the regulator can be expected.

Formal Reports

The audit team leader is responsible for providing the regulatory organisation with a formal report which will provide details of all findings together with audit conclusions and where appropriate auditor perceptions. Following receipt of this report the appropriate management function in the regulatory organisation will need to communicate formally with the audited organisation setting out the key areas of concern and the actions required by the regulator - such as corrective actions. It is necessary for the audit team leader to prepare a report for use within the regulatory organisation. This may require an "Executive Summary" which should be prepared with the busy executive in mind and should clearly and succinctly convey:

Objectives & Scope
Conclusions
An overview of findings
Recommendations.

It is the responsibility of the regulatory organisation to provide a formal written response to the audited organisation following an audit, in order to communicate clearly the actions that the regulatory organisation requires of the audited organisation in order to respond to audit findings. This communication may not detail the audit findings themselves as these will have been left with the audited organisation, however it will refer to key findings for which the regulator requires a formal response. It is important to remember that the communication should hold no surprises, and it should reflect accurately what was presented at the closing meeting. This communication may be prepared by the audit team leader on behalf of the regulatory organisation.

Reports

REMEMBER WHO IS THE RECIPIENT
REMEMBER WHAT THE RECIPIENT NEEDS

SUMMARISE FINDINGS

PROVIDE THE DETAILS

THINK BEFORE WRITING AND
WRITE CLEARLY & CONCISELY

DRAW CONCLUSIONS

Contents for a typical audit report.

Report identification

Confidentiality clause.

Purpose, objective and scope of the audit.

Details of the audit programme, auditors, dates and organisation in which the audit was conducted.

Identification of the reference documents against which the audit was conducted (Regulations, auditee Manual/Exposition, etc.).

Summary of findings.

Audit observations, non-conformities and supporting evidence.

Recommendations for follow-up of corrective action and for subsequent audits.

Reference to supporting documents, attached as required.

Conclusions of the audit team, judgements as to the degree of compliance with the Regulations and the systems ability to achieve defined objectives.

Distribution List.

The audit report should be signed and dated by the team leader, and sent to the client/audited company. As the report is confidential it should not be distributed outside of the audit organisation without the permission of the audited company.

The Corrective Action Process.

The audit has been completed once the auditors have conveyed the findings to the appropriate regulatory management function (verbally and in writing).

It is recommended that the audit life cycle is split into two separate processes. The audit itself and the corrective action phase.

IT IS A PRIME RESPONSIBILITY OF THE AUDITOR(S) TO COMPLETE THE AUDIT PROCESS AND PROVIDE MANAGEMENT WITH DETAILS OF THE FINDINGS

The Regulatory management function responsible for continued approval decisions is fully responsible for the determination and implementation of appropriate corrective action in a timely manner to ensure that system weaknesses are rectified as soon as practicable.

However, the regulators audit management function should be satisfied that corrective action proposed will deal with the root cause of the problem and when implemented is fully effective in eliminating the noncompliance found.

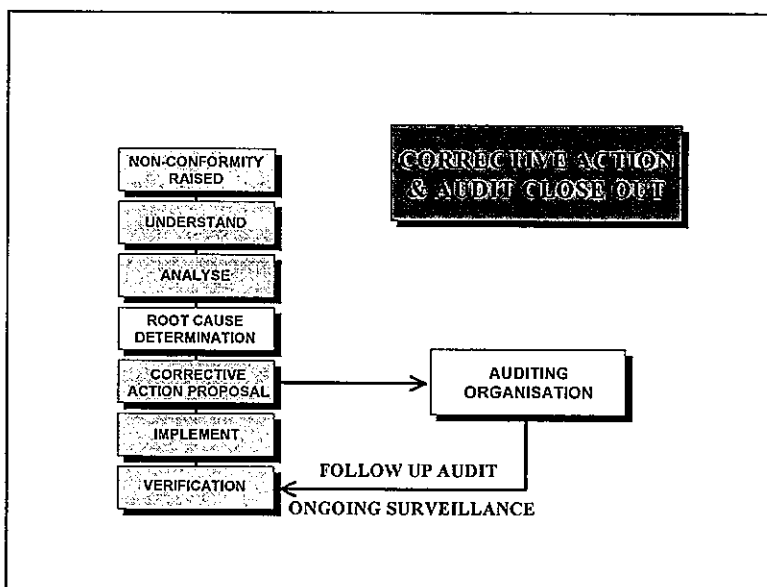
It is important to recognise that the audited organisations management are fully responsible for determining suitable corrective actions and appropriate timescales, however the regulatory organisation may need to define timescales based on safety regulatory concerns.

Should effective corrective action not be taken, or no indication given as to when it will be fully considered, then audit management must refer the matter to higher authorities once all other means of eliciting a suitable response have been exhausted. This may be when a regulator considers the need for enforcement action.

Once corrective action has been implemented then audit management should arrange for formal verification that it is effective in overcoming the original noncompliance. This may, or may not, involve the original audit team.

Audit Management need to be satisfied that the corrective action is taken and effective, this should be formally recorded (preferably on the original audit report form) and the audit 'closed out'. This check on the effectiveness of the corrective action is aimed at establishing that the root cause of the problem has been addressed and that the problem ('symptoms') found on the initial audit is no longer evident. This will require appropriate audit samples to check for the problem previously noted in appropriate areas of the organisation.

It may be useful to check the ongoing effectiveness of any corrective actions again at subsequent oversight audits.



Follow-Up and Surveillance Visits

It is usual upon completion of an audit to establish a formal activity to verify the implementation of corrective actions. This should be performed at an appropriate mutually agreed time following the audit, and after receiving details of corrective actions proposed together with associated timescales. It is usually possible for the Team Leader, or a member of the original audit team to undertake this activity, however in some organisations it is delegated to some other local representative or agent.

For many audits non-conformances of a relatively minor nature only are required to be addressed before formal approval/certification is granted. In these situations it is normal for the Team Leader to verify adequate implementation of the corrective action agreed either at the time of audit, or shortly after, possibly two or three months following the audit visit.

However for more major non-conformances it may be necessary to allow a greater period of time and undertake a limited re-audit. (Dependent upon the severity of the nonconformities such a re-audit may be as in-depth as the original audit and to a similar schedule).

Where required by the 'client' the Team Leader will review proposals for corrective action and decide if fully appropriate, arrangements may then be made to verify full implementation of such either by the Team Leader, another member of the team, or another local representative. Some very minor documentation non-conformances may be corrected and verified by the Team Leader viewing correspondence only, others will require a "Follow Up" visit to be made. It is important to recognise that when examining corrective action proposals the focus of attention should be establishing that the proposal shows clear signs of a thorough investigation having been carried out by the audited organisation to determine the 'root cause' of the problems revealed by the auditor(s). It is all too easy for the audited organisation to propose corrective actions that merely hide the symptoms rather than deal with the cause of the problem.

When follow up visits are made, the detail originally entered onto the non-conformance reports is vital information for the verifying party and so emphasises the need for such information to be clear, complete and traceable.

If corrective action taken is found to be effective then the non-conformance report is signed off and the audit closed out.

For Regulatory Authorities there may be a specific on-going surveillance activity performed by a separate group within the regulatory authority, or by a local representative who keeps close contact with the organisation.

