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COMBINEDQMS/ISM LEADAUDITOR/AUDITOR TRAININGCOURSE

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QUALITY MANAGEMENT SYSTEMS

LEAD AUDITOR/AUDITOR TRAINING

COMBINED QMS/ISM LEAD AUDITOR/AUDITOR TRAINING COURSE

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ISO/ISM AUDITOR TRAINING COURSE PROGRAMME

DAY 1	0800	Registration
	0830	Introductions (Including Activity 1)
	0900	Review of Course Style/Administration/Examination
	0915	Introduction of Quality
	0925	Concerns/Expectations about Quality/Safety Man. Sys.
	0940	Introduction to Quality Management
	1030	Morning Break
	1045	Activity 2
	1115	Activity 3
	1155	Present Findings - Activity 3
	1215	Introduction to Quality Management (Continued)
	1230	Lunch
	1330	Introduction to Quality Management
	1430	Quality Management – Principles and Practice
	1530	Afternoon Break
	1545	Quality Management – Principles & Practice (Continued)
	1730	Activity 4
	1800	Review Activity 4
	1830	Quality Management (Continued)
	1845	Close
DAY 2	0830	Recap of Day 1
	0845	Review of ISO 9001:2000 Element 7
	1030	Morning Break
	1045	Recap Element 7
	1100	Activity 5 – Understanding the Elements of ISO 9001:2000
	1230	Lunch
	1330	Activity 5 (Continued)
	1400	Review Activity 5
	1600	Afternoon Break
	1615	Introduction to the Audit Process
	1745	Activity 6
	1815	Review Activity 6
	1830	Introduction to the Audit Process (continued)
	1900	Close
DAY 3	0830	Recap on Day 2
	0845	Introduction to ISM Safety Management System
	1030	Morning Break
	1045	Activity 7 – Understanding the Intent of the ISM Code
	1230	Lunch
	1330	Implementing the Requirements of the ISM Code
	1530	Afternoon Break
	1545	Risk Assessment
	1645	Activity 8 – Identifying and Controlling Risk
	1715	Activity 8 - Presentations
	1745	Relationship between ISO/ISM incl. Non-Conformances
	1815	Coffee Break
	1830	ISM Examination (One Hour)
	1930	Close

ISO/ISM AUDITOR TRAINING
COURSE PROGRAMME (Continued)

DAY 4	0830	Recap on Day 3
	0845	Planning and Preparing for an Audit
	1030	Morning Break
	1045	Planning and Preparing for an Audit (Continued)
	1100	Activity 9 – Planning an Audit (The Process Approach)
	1230	Lunch
	1330	Activity 9 – Presentations
	1415	Activity 10 - Checklists
	1500	Afternoon Break
	1515	Activity 10 – Checklists (Continued)
	1600	Presentations and Discussions
	1700	Audit Performance – An Overview
	1830	Close

DAY 5	0830	Review of Course (Up to this Stage)
	0845	Activity 11 – The Audit Scene (Including Team Presentations)
	1015	Morning Break
	1030	Activity 11 Presentations (Continued)
	1100	The Auditor's Tools
	1230	Lunch
	1330	Corrective Action Requests
	1400	Activity 12 - Writing a CAR
	1430	Exit Meeting/Reporting the Audit and Audit Follow-up
	1515	Afternoon Break
	1530	Exit Meeting/Reporting the Audit and Audit Follow-up (Continued)
	1600	Auditor Training and Qualifications
	1630	Activity 13 – The ISM/ISO Challenge
	1830	Review of Sample Specimen Exam Paper
	1900	Close

DAY 6	0830	Recap of Course
	0845	Activity 14 – Case Study "Super Cruise Line"
	1030	Morning Break
	1045	Activity 14 (Continued)
	1200	Course Recapitulation
	1230	Lunch
	1330	Course Recapitulation (Continued)
	1430	Course Questionnaire
	1500	Examination (Two Hours)
	1700	End of Course

PART 1

Foreward **1.1**
Examination Criteria **1.3**

FOREWORD

For the benefit of those who wish to become registered as an Auditor or Lead Auditor, it should be understood that successful completion of this Course will not meet all requirements for registration. Indeed, it is to be emphasised that successful completion of the Course will satisfy only the training requirements of the International Register of Certificated Auditors (IRCA){formerly the RBA} and the other bodies who support the International Registration Scheme. There are other requirements relating to education, industrial experience and quality management experience that must also be satisfied. The requirements for registration will be dealt with as part of this Course Programme.

For the purpose of this Course, the term *Assessment* is being used to relate to a pre-contract award activity, which is undertaken to evaluate a potential Supplier, and the term *Audit* to post-contract award and internal activities. It is to be understood, however, that outside of this Course the two terms are used interchangeably but it is felt necessary to differentiate between *Audit* and *Assessment* if only to place the importance on the pre-contract award activity. However, the techniques in both instances are the same but there are some differences in team skills and documentation. These differences will be covered in detail.

Assessing and auditing skills can be achieved only under actual conditions but such conditions can be simulated to a certain extent in the Lecture Room by the use of Workshops and Role Plays. Full use of such aids will be made throughout the duration of the Course. The Course is designed to meet the following objectives:

- Describe the purpose of a Quality management System and explain the eight (8) principles of Quality Management.

- Describe the purpose of a Safety Management System and the ISM Code requirements.

- Explain the purpose, content and inter-relationship of ISO 9000, ISO 9001, ISO 9004 and ISO 19011:2002.

- Interpret requirements of ISO 9001 and the ISM Code in the context of an Audit.

- Describe roles and responsibilities of Auditors and Lead Auditors.

- Plan and conduct an Audit in accordance with ISO 19011, demonstrating ability to:

  a) Plan and prepare effectively.
  b) Gather objective evidence, through effective interviewing, observation, sampling and note taking.
  c) Analyse and interpret information in order to determine conformance with requirements.

- Report the Audit, including writing valid, factual and value-adding non-conformity reports.
- Undertake Audit follow-up activities, including evaluating the effectiveness of corrective actions.
- Explain the similarities between the ISM Code and the ISO 9000 series and identify any areas where one complements the other.
- Explain the rationale supporting the implementation of the ISM Code and state the implementation timescales.
- Plan and prepare an audit to the requirements of the ISM Code with respect to the management of an organisation and the operation of a ship.
- Distinguish between the process for the issue of a Document of Conformance (DOC) and the process for the issue of a Safety Management Certificate (SMC).

As a result, this course has been developed to incorporate the requirements of the following International Standards and Codes:

*	ISO 19011:2002	Guidelines for Quality and/or Environmental Systems auditing.
*	ISO 9001 : 2000	Quality Management Systems – requirements.
*	ISO 9000 : 2000	Quality Management Systems – fundamentals & vocabulary.
*	ISO 9004 : 2000	Quality Management Systems – Guidelines for performance improvements
*	ISM Code	Resolution A741(18) 1993 as adopted by SOLAS Chapter IX (Amended July 2002

COURSE EXAMINATION CRITERIA

TIMING: AS PER THE COURSE PROGRAMME.

DURATION: 2.0 HOURS.

FORMAT:

THE ISM EXAMINATION PAPER IS IN ONE (1) SECTION AND THE ISO PAPER IS IN FOUR (4) SECTIONS. THE MAXIMUM MARKS AVAILABLE ARE TWENTY 20 (ISM) AND 80 (ISO) RESPECTIVELY. YOU ARE REQUIRED TO ACHIEVE AT LEAST 40% IN EACH SECTION (ISO). THE OVERALL PASS MARK FOR THE EXAMINATION IS 75%. WHERE A CANDIDATE ACHIEVES BETWEEN 50% AND 74% IN THE EXAMINATION A RE-SIT WILL BE OFFERED, PROVIDED THE CONTINUOUS ASSESSMENT IS SATISFACTORY. THERE IS NO RE-SIT OPTION FOR A CANDIDATE WHO ACHIEVES LESS THAN 50% IN THE EXAMINATION.

RESULTS:

VIA YOUR COURSE CO-ORDINATOR.

COURSE CERTIFICATE:

IN ADDITION TO OBTAINING THE REQUIRED MINIMUM PASS MARK IN THE WRITTEN EXAMINATION, YOU MUST ACHIEVE AT LEAST 70% IN THE CONTINUOUS ASSESSMENT FOR SUCCESSFUL COMPLETION OF THE COURSE. FULL ATTENDANCE IS REQUIRED. TIME KEEPING WIL BE RECORDED AS PART OF CONTINUOUS ASSESSMENT.

FOR THOSE ACHIEVING 75% AND ABOVE IN THE WRITTEN EXAMINATION AND 6 AND ABOVE IN EACH SECTION OF THE CONTINUOUS ASSESSMENT A CERTIFICATE WILL BE FORWARDED TO YOUR COURSE CO-ORDINATOR WITHIN 10 WORKING DAYS OF THE EXAMINATION.

FOR I.R.C.A PURPOSES THE CERTIFICATE HAS A VALIDITY OF THREE YEARS

CERTIFICATE OF ATTENDANCE:

ISSUED FOR THOSE ACHIEVING 50% OR LESS IN THE EXAMINATION. FORWARDED TO YOUR COURSE CO-ORDINATOR WITHIN FOURTEEN (14) WORKING DAYS OF EXAMINATION.

PART 2

INTRODUCTION

General	**2.1**	
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2.1

INTRODUCTION

GENERAL

The Oxford dictionary defines quality as a *degree of excellence* or *relative nature.* Quality, therefore, is like beauty, which is in the eye of the beholder. What is considered by one person to be of good quality could be considered by another to be of poor quality and vice versa. However, in the context of quality assurance, quality has a precise meaning, which the International Standard 9000:2000 defines as:

Degree to which a set of inherent ***characteristics*** *fulfils* ***requirements.***

Requirements can be stated, generally implied or obligatory. It is, therefore, necessary to understand the requirements of the Customer and what the Customer means by quality if the product or service is to satisfy the need. In a consumer society the requirements of the Customer can be identified only by Market Research and Information gained this way must be fed back to the Finance, Design, Production or Service Departments for review for feasibility and implementation (these are the 'implied needs' of the ISO definition). In the case of major items, then the requirements must be identified by the Customer in the form of detailed specifications - the stated needs.

In other words: What is the item required to do? What are the service requirements? What shape, size and colour is required? What is the expected service life and how is it to be disposed of when its usefulness has come to an end?

The importance of the disposal of an item is often overlooked. Much will depend upon its size and complexity. In the case of small consumer items, disposal should be comparatively simple but for capital plant, consideration should be given at the outset to its ultimate decommissioning and dismantling.

ASSURANCE OF QUALITY

In order to assure quality, it is necessary first to ensure that all the requirements are known. In other words, the customer's requirements must be sufficiently detailed to be fully understood by the supplier so that there are no areas of doubt as to the item or service requirements.

This is the sine qua non of any Quality Management System. The gathering together of all the information, the planning of all activities and the detailing of precise instructions should all take place before any activity commences. The subsequent proper control of these activities then becomes possible.

Quality Assurance requires the total integration and control of all elements of an operation so that none is subservient to the other. These elements cover such aspects as Administration, Finance, Sales, Marketing, Design, Procurement, Manufacture, Installation, Commissioning and even Decommissioning.

If all the elements of an operation are to be totally integrated so that none is subservient to the other, the role, or function, of each of these elements should first be established and there should be a person to bring them all together. Therefore, responsibility should be assigned for the establishment of requirements and the integration and control of all activities. Ultimately, it is the Senior Executive of an Organisation who must accept responsibility for this direction and for the quality of the items or services produced by his/her Organisation.

Quality Assurance is, therefore, a Management function, which cannot be delegated. A properly constituted Quality Assurance Department can produce a plan for action and a system to be followed but its implementation is a Management responsibility. Quality is not something that can be 'tacked on' to a manufacturing or a service process; Quality Assurance is a philosophy of total integration of the business to achieve the required result.

QUALITY AND QUALITY STANDARDS

The International standard 9000:2000 defines quality as:

Degree to which a set of inherent ***characteristics*** *fulfils* ***requirements.***

This definition clearly depends upon understanding those requirements.

Higher specification and higher quality must not be confused here. For example, a Rolls Royce will have a higher specification than a Proton yet both satisfy a ‘given need’. The needs are different and both can be good quality or poor quality.

Quality can be regarded as having two separate dimensions.

The external dimension of quality is all about delighting the **External Customer** by providing complete customer satisfaction - by being the best at the things that matter most to them.

The internal dimension of quality is about doing things right first time, thereby satisfying the external customer at lowest cost to the Company. This is achieved by a full understanding of **Internal Customer** requirements. Internally it is about doing things right.

ISO 9000:2000 provides a definition of quality terms as a Quality Vocabulary and has a direct application to the International Standards on quality systems.

THE EVALUATION OF QUALITY MANAGEMENT

Quality probably began around the time of the Egyptians and the building of the Pyramids.

The next major influence was at the time of the Industrial Revolution and the building of the Railways.

Quality Control, as we know it today really began during the First World War when it became necessary to produce large quantities of armaments from a widely varied number of suppliers in a short time. A high level of inspection controlled Quality.

Quality Management as we know it really began during and following the Second World War. When the failure rate of equipment and munitions identified the need for greater enhancement of Quality Systems with a particular need for **prevention** rather than detection of problems and systems to maximise output and to provide assurance of the 'fitness for purpose' of product.

Quality systems have evolved rapidly in recent years. Simple inspection activities were first replaced or supplemented by *Quality Control* systems. Subsequently, *Quality Assurance* was developed and refined and the more progressive organisations are now working towards *Total Quality Management.* In reviewing this progression, four significant stages can be identified: -

(a) Inspection
(b) Quality Control
(c) Quality Assurance
(d) Total Quality

There have been several distinct changes in the way quality has been viewed.

Inspection

Under a simple inspection based system, one or more characteristics of products are examined, measured and compared with specified requirements to assess conformity. The system is applied to incoming goods, manufactured components and assemblies at appropriate points throughout the manufacturing process. Inspection is carried out mainly by staff employed specifically for the purpose. Goods or products, which do not conform to specification, may be scrapped, re-worked or passed, on concession. In some cases inspection is used to grade the finished product. The system is an <u>after-the-fact</u> screening process and is <u>detection</u> based with no prevention content other than, perhaps, identification of suppliers, operations or workers producing non-conforming products. Simple inspection-based systems are usually wholly in-house and do not involve suppliers or customers directly.

Quality Control

Where a system of *Quality Control* is used, more widespread checking and specification systems would be apparent. These would include drawing control system, raw material and intermediate product testing, some self-inspection by operators, logging of elementary process performance data and feedback of process information of operative, setters and production supervisors. While the main mechanism for preventing products, which are outside specification, from being shipped to customer, is again screened, i.e. detection. *Quality Control* measures lead to greater process control and a lower incidence of non-conformance. Use of this type of system came in the 1950's with increased mass production and higher demand for consumer goods. More efficient use of materials, which were in short supply, was required and profit margins assumed much greater importance.

Quality Assurance

Can be considered to be the part of the quality management, focused on providing confidence that the quality requirements will be fulfilled.

The additional features acquired when progressing from Quality Control to Quality Assurance include a more comprehensive quality manual, developing procedures and limited use of quality costs; use of statistical process control (SPC); advance quality planning and auditing of **quality systems**.

The primary change would be a move from simple detection towards prevention of non-conformance.

Many purchasers now require suppliers to be assessed by representatives of the purchaser's organisation against <u>their</u> specific Quality System requirements or to be able to demonstrate on-going registration to a recognised National/International Standard for Quality Systems.

These reviews are known as Third Party approvals and are achieved by the undertaking of initial assessments of the Auditing Organisations planned, documented, and implemented systems and subsequent periodic surveillance audits to ensure on-going conformance and adequacy.

Such accreditations are controlled and governed in the UK by the United Kingdom Accreditation Service (U.K.A.S) who in turn are controlled by the Department of Trade and Industry (DTI).

With increasing competition, more sophisticated consumers, and the demand for higher specification product, the pressures on manufacturers increase constantly. In order to survive the effects of low profit margins and short product life, the manufacturer must strive for efficiency in all the Internal Systems of the company.

Total Quality Management

The final stage of evolution was to be Total Quality Management. This is both a natural extension of the influence of Quality Systems and also, perhaps, a move to regain some of the advantages enjoyed by the craftsmen of old. Here the focus is centred on the involvement of people, both individually and as members of groups or teams.

The goal is always to promote **prevention** of non-conformance rather than, as with previous systems, heavy dependence on **detection.** In this sense it concentrates on activity before the fact by understanding potential problems and planning to avoid them. Such organisations often use Quality Planning, Failure Mode and Effects Analysis, fool- proofing and other tools and techniques as a means of product and system development.

The 'culture' of the company stresses the need for employees to strive for continual improvement. The quality system is not a set standard method of operation handed down by management, but a constantly changing set of guidelines, changed and improved by analysis and experience.

Total Quality is dedicated to meeting the needs of both internal and external customers and continuously attempting to improve the standards achieved. Working within the framework of a documented quality system supplies the processes that can be studied and controlled. By promoting the widespread involvement of individuals and team working, the organisation can build a culture of continuous improvement, concentrating on prevention rather than detection of non-conformance.

Prevention as a Basis for a System

Inspection is based upon finding errors. Someone finds them, someone corrects them. This is a very costly approach, long term, for a company to take.

Prevention is based upon stopping errors happening. Although a system based upon prevention may cost more short term, long term it is by far the least expensive route to take.

Inspection has other problems. It means the customer suffers and where errors are few and far between, for example in high technology products where defect rates can be measured in parts per billion - it simply doesn't work.

The only way to operate a system like this is to have a basis of **prevention**. After all - we only inspect because we expect there to be faults. If we knew that no faults were present we would not inspect. The way forward is to build a system based upon prevention by using such techniques as Failure Mode and Effect Analysis and other tools and techniques.

Quality Management Systems and Prevention

The whole basis of a quality management system is prevention. A quality management system is the organisational structure, the responsibilities, the procedures, processes and resources for implementing Quality Management.

In other words it details the responsibility and how that responsibility is translated into action in a company.

***BS EN* ISO 9001:2000**

BS 5750 Parts, 1, 2 and 3 were first published in 1979

In 1987 The International Standards Organisation (ISO), the European Committee for Standardisation (CEN), and the Department of Trade and Industry in conjunction with the British Standards Institute (BSI) agreed on the formation and format for equivalent International/European/and British National Quality System Standards to be known as: -

BS 5750:	1987 Series:	British Standard
ISO 9000:	1987 Series:	International Standard
EN 2900:	1987 Series:	European Standard

The content requirement of each part of the Standard series was to be the same and all would be subject to a five-year review by Joint Review of members.

Registration by an accredited registration body under the above Standards would provide common registration and recognition worldwide to the equivalent Standard.

The first revision to the 1987 ISO/EN/BS Standards was planned for 1992 in accordance with ISO Directives and was published in 1994 as ***BS EN ISO 9000:1994.***

In 1996 a second review of ISO 9000 was initiated, this review was completed and the latest version published on 15th December, 2000 is known as **ISO 9001:2000**.

Under ISO protocols all International Standards are required to be reviewed every five (5) years to determine if they should be confirmed, revised or withdrawn.

The 2000 revision has four (4) Core Standards of which only one (ISO 9001:2000) is auditable.

1.	ISO 9000:	Fundamentals and Vocabulary.
2.	ISO 9001:	Quality Management System Requirements.
3.	ISO 9004:	Guidelines for Performance Improvements.
4.	ISO 19011:	Guidelines on Quality and Environmental Auditing.

PRODUCT QUALITY

3000 BC	Babylonia – uniform units for weights and measures.
11th C	England – Guild Act creates uniformity in places of manufacture.
1456	Inspection becomes a production activity – Henry VI.
1631	Patterns for arms and armour – Charles I.
18th C	Physical samples and standards used for comparison purposes.
Late 19th C	Formal inspection departments now exist. Physical standards and samples replaced by written instructions.
Early 20th C	Defence ordnance standards written.
1920	Large number of product standards now available.
1924	Quality control formally recognised. In-process and final inspection identified as essential QC functions.
1940's	QC expands to incorporate checks of design processes, product life-cycle and reliability programmes etc…
1950's	Juran and Deming teach QC concepts in post war Japan.
1960's	Integration of product design, manufacture and delivery activities into the discipline of quality assurance.
1974	BS 5719 Quality systems standard published
1979	BS 5750 Quality systems standard replaces BS 5719
1987	ISO 9000 series of quality system standards published (issued without variation as BS 5750-1987)
1994	ISO 9000 revised with minor amendments and some changes in emphasis (issued in UK as BS EN ISO 9000)
2000	December 15th revised standard issued, more user friendly and now process based.

ISM CODE

The International Management Code for the Safe Operation of Ships and for Pollution Prevention (ISM Code) was made mandatory in 1994 by the adoption of Chapter IX of SOLAS '74. It became mandatory for Passenger Ships, Oil Tankers, Gas Carriers, Chemical Tankers, Bulk Carriers, Ro-Ro's and High Speed Craft on 1st July, 1998 and all remaining vessels over 500 GRT complied by 1st July 2002.

The introduction of this international requirement for operating ships and pollution prevention was as a result of a growing number of marine disasters which were clearly due to a lack of good Management systems and operating practices and ensuring that good effective practices were carried out onboard ship. The inquiry into the "Herald of Free Enterprise" highlighted many of the now common place management deficiencies found in shipping companies and prompted the United Kingdom Department of Transport to issue 'M' Notice 1353 setting out recommended Operating Procedures. This was used as the basis of IMO's Resolution 647 in 1989, which was itself, up-dated to Resolution 680 in 1991 and finally became Resolution A741 (18) in 1993, the adopted wording of Chapter IX of SOLAS '74. The Code was amended in December 2000 by resolution MSC.104(73). This resolution was accepted on 1st January 2002, and these amendments entered into force on 1st July 2002.

The operation of merchant shipping is specialised and complex, governed by comprehensive rules and conventions developed by National and International Authorities. Nevertheless, regulation of the technical aspects of shipping can only achieve part of the objective of safe pollution-free ship operations. In the final analysis, while the Master is clearly responsible for the safety of the ship and her crew, the overall responsibility for the Administration and safe operation of each ship rests with the Owner or any other organisation or person who has assumed the responsibility for the operation of the ship from the Owner.

The task facing all shipping companies is to minimise the scope of poor human decisions that contribute directly or indirectly to a casualty or pollution incident. One aim should be to ensure that staff are properly informed and equipped to fulfil their operational responsibilities safely. Decisions taken ashore can be as important as those taken at sea and there is a need to ensure that every action affecting safety or the prevention of pollution, taken at any level within the company is based on a sound understanding of its consequences.

The ISM Code establishes an International Standard for the safe operation of ships by setting Rules for the organisation of Company Management in relation to safety and pollution prevention and for the implementation of a Safety Management System (SMS).

A Safety Management System (SMS) meeting the requirements of the ISM Code requires a Company to document its Management Procedures and record its actions to ensure that conditions, activities and tasks that affect safety and environment are properly planned, organised, executed and checked. A SMS is developed and implemented by people and clearly defines responsibilities, authorities and lines of communication. It allows a Company to measure its performance against set criteria, hence identifying areas that can be improved. It does not replace the requirement for conformance with existing international and national rules and regulations.

ISM CODE DEVELOPMENT - CHRONOLOGICAL ORDER OF PRINCIPAL EVENTS	
DATE	**EVENTS AND COMMENTS**
July 1986	Issue by UK of Notice M1188. Non-Mandatory advice on Good Management following a Court of Formal Investigation report critical of Ship Management. Recommends a "Designated Person Ashore" responsible for safe operation.
June 1987	H.O.F.E. Court of Formal Investigation Report: "M1188 provides should advice".
April 1988	IMO: MSC 55: UK Proposals for passengers Ro-Ro ferries to carry Operations Book and have "Designated Person Ashore"; no time for discussion. IMO Guidelines on Safe Ship Management to be developed.
October 1988	IMO: MSC 56: UK proposals for passenger Ro-Ro ferries considered but not accepted (see MSC 55 above).
December 1988	UK Regulation for UK passenger Ro-Ro ferries only. Requirements include "Designated Person Ashore" and carriage of an Operations Book.
24th March 1989	Exxon Valdez grounded on Bligh Reef in Prince William Sound which led directly to the implementation of OPA 90 and double hull tankers.
April 1989	IMO: MSC 57: UK delegation expresses concern at omission of reference to a "Designated Person Ashore" from Non-mandatory Draft Guidelines.
April 1990	"Scandinavian Star" Disaster.
May 1991	IMO: MSC 59: Nordic proposals based on ISO 9000, for a mandatory S. M. S. for passenger ships and other ships over 5000 grt. IMO Working Group amends Resolution A647 (16) to include a "Designated Person Ashore". Work commenced on ISM Code.
November 1991	IMO: 17th Assembly: Adoption of Resolution A680 (17) that includes a "Designated Person Ashore" and cancels Resolution A647 (16).
February 1992	Select Committee under the Chairmanship of Lord Carver, House of Lords report makes recommendation for: "that the EC should adopt a standard of verifiable Safety Management System for shipping, based on ISO 9002 and IMO Resolution A647, and impose it as a compulsory requirements for ships of any Flag, carrying passengers, oil or hazardous cargoes in EC waters".
May 1993	IMO: MSC 62: Approval of Draft ISM Code for submission to the Assembly. Work commenced on IMO Guidelines on ISM Code Implementation. Decision to make ISM Code mandatory.
November 1993	IMO: 18th Assembly: ISM Code adopted under Resolution A741 (18). Resolution A739 (18) on Standards of Recognised Organisations. ICS/ISF Guidelines for Companies on Application of ISM Code submitted.
May 1994	IMO: Conference of Contracting Governments to SOLAS: ISM Code made mandatory for passenger ships and all other ships and MODUs over 500 gt on staggered implementation dates. Standards for **Recognised Organisations** made mandatory under Resolution A739 (18).
February 1995	IMO: Flag States Implementation Sub-Committee completes "Guidelines on the Implementation of the ISM Code by Administrations" except for the format for the certificates.
1st July, 1998	Implementation for Passenger Ships, Tankers, Bulk Carriers, Oil Tankers, Gas Carriers and Chemical Tankers.
1st January 2002	IMO:MSC 104(73) ISM amendment accepted. (Code now in two parts A & B and 16 elements)
1st July 2002	Implementation for remainder of ships over 500 GT, and entry into force of IMO:MSC 104(73).
1st July 2004	Entry into force of the International Ship and Port Facility Security Code (ISPS Code) Resolution A.924(22). Although this is not part of the ISM code there are certain similarities e.g. schedules and drills.

2.10

TERMS AND DEFINITIONS

A Term in a Definition or note, which is defined elsewhere in this Clause, is indicated by **boldface**. Such a **boldface** Term may be replaced in the Definition by its complete Definition. For example:

"Product" is defined as "Result of a **Process**".

"Process" is defined as "Set of interrelated activities that transforms inputs into outputs".

If the term **"Process"** is replaced by its definition as follows:

Product then becomes "Result of a set of interrelated or interacting activities which transforms inputs into outputs".

A concept limited to a special meaning in a particular context is indicted by designating the subject field in angle brackets **< >** before the definition, for example**, Technical Expert** <Audit>.

TERMS RELATING TO QUALITY

Quality:
Degree to which a set of inherent **characteristics** fulfils **requirements**.

Requirement:
Need or expectation that is stated, generally implied or obligatory.

Grade:
Category or rank given to different Quality **requirements** for **products**, **processes** or **systems** having the same functional use.

Customer Satisfaction:
Customer's perception of the degree to which the customer's **requirements** have been fulfilled.

Capability:
Ability of an **Organisation**, **system** or **process** to realise a **product** that will fulfil the **requirements** for that product.

TERMS AND DEFINITIONS (Continued)

TERMS RELATING TO MANAGEMENT

System:
Set of interrelated or interacting elements.

Management System:
System to establish Policy and Objectives and to achieve those Objectives.

Quality Management System:
Management System to direct and control an **Organisation** with regard to **Quality**.

Quality Policy:
Overall intentions and direction of an **Organisation** related to **Quality** as formally expressed by **Top Management**.

Objective Evidence:
Something sought, or aimed for, related to **Quality**.

Management:
Co-ordinated activities to direct and control an **Organisation**.

Top Management:
Person or Group of people who direct and control an **Organisation** at the highest level.

Quality Management:
Co-ordinated activities to direct and control an **Organisation** with regard to **Quality**.

Quality Planning:
Part of **Quality Management** focused on setting **Quality Objectives** and specifying necessary operational **processes** and related resources to fulfil the Quality Objectives.

Quality Control:
Part of Quality **Management** focused on fulfilling Quality **requirements**.

Quality Assurance:
Part of **Quality Management** focused on providing confidence that Quality **requirements** will be fulfilled.

Quality Improvement:
Part of **Quality Management** focused on increasing the ability to fulfil Quality **requirements**.

TERMS AND DEFINITIONS (Continued)

Continual Improvement
Recurring activity to increase the ability to fulfil **requirements**.

Effectiveness:
Extent to which planned activities are realised and planned results achieved.

Efficiency:
Relationship between the result achieved and the resources used.

TERMS RELATING TO ORGANISATION

Organisation:
Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

Organisational Structure:
Arrangement of responsibilities, authorities and relationships between people.

Infrastructure:
<Organisation> system of facilities, equipment and services needed for the operation of an **Organisation**.

Work Environment:
Set of conditions under which work is performed.

Customer:
Organisation or person that receives a **product**.

Supplier:
Organisation or person that provides a **product**.

Interested Party:
Person or group having an interest in the performance or success of an **Organisation**.

TERMS AND DEFINITIONS (Continued)

TERMS RELATING TO PROCESS AND PRODUCT

Process:
Set of interrelated or interacting activities that transform inputs into outputs.

Product:
Result of a **process**.

Project:
Unique **project** consisting of a set of co-ordinated and controlled activities with start and finish dates, undertaken to achieve and objective conforming to specific **requirements** including the constraints of time, cost and resources.

Design and Development:
Set of **processes** that transform **requirements** into specified **characteristics** or into the **specification** of a **product**, **process** or **system**.

Procedure:
Specified way to carry out an activity or a **process**.

TERMS RELATING TO CHARACTERISTICS

Characteristics:
Distinguishing feature.

Quality Characteristics:
Inherent characteristic of a **product**, **process** or **system** related to a **requirement**.

Dependability:
Collective terms used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance.

Traceability:
Ability to trace the history, application or location of that which is under consideration.

TERMS AND DEFINITIONS (Continued)

TERMS RELATING TO CONFORMITY

Conformity:
Fulfilment of a **requirement**.

Non-conformity:
Non-fulfilment of a **requirement**.

Defect:
Non-fulfilment of a **requirement** related to an intended or specified use.

Preventive Action:
Action to eliminate the cause of a potential **non-conformity** or other undesirable potential situation.

Corrective Action:
Action to eliminate the cause of a detected **non-conformity** or other undesirable situation.

Correction:
Action to eliminate a detected **non-conformity**.

Re-work:
Action on a non-conforming **product** to make it conform to the **requirements**.

Re-grade:
Alteration of the **grade** of a non-conforming **product** in order to make it conform to **requirements** differing from the initial ones.

Repair:
Action on a non-conforming **product** to make it acceptable for the intended use.

Scrap:
Action on a non-conforming **product** to preclude its originally intended use.

Concession:
Permission to use or release a **product** that does not conform to specified **requirements**.

Deviation Permit:
Permission to depart from the originally specified **requirements** of a **product** prior to realisation.

Release: Permission to proceed to the next stage of a **process**.

TERMS AND DEFINITIONS (Continued)

TERMS RELATING TO DOCUMENTATION

Information:
Meaningful data.

Document:
Information and its supporting medium.

Specification:
Document stating **requirements**.

Quality Manual:
Document specifying the **Quality Management System** of an **Organisation**.

Quality Plan:
Document specifying which **procedures** and associated resources shall be applied by whom and when to a specific **project**, **product**, **process** or contact.

Record:
Document stating results achieved or providing evidence of activities performed.

TERMS RELATING TO EXAMINATION

Objective Evidence:
Data supporting the existence or verity of something.

Inspection:
Conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging.

Test:
Determination of one or more **characteristics** according to a **procedure**.

Verification:
Confirmation, through the provision of **objective evidence** that specified **requirements** have been fulfilled.

Validation:
Confirmation, through the provision of **objective evidence** that the **requirements** for a specific intended use or application have been fulfilled.

TERMS AND DEFINITIONS (Continued)

Qualification Process:
Process to demonstrate the ability to fulfil specified **requirements**.

Review:
Activity undertaken to determine the suitability, adequacy and **effectiveness** of the subject matter to achieve established objectives.

TERMS RELATING TO AUDIT

Audit:
Systematic, independent and documented **process** for obtaining **Audit evidence** and evaluating it objectively to determine the extent to which **Audit criteria** are fulfilled.

Audit Programme:
Set of one or more **Audits** planned for specific time frame and directed towards a specific purpose.

Audit Criteria:
Set of Policies, **Procedures** or **requirements** used as a reference.

Audit Evidence:
Records, statements of fact and other **information**, which are relevant to the **Audit criteria** and verifiable.

Audit Findings:
Results of the evaluation of the collected **Audit evidence** against **Audit criteria**.

Audit Conclusion:
Outcome of an **Audit** provided by the **Audit Team** after consideration of the Audit objectives and all **Audit findings**.

Audit Client:
Organisation or person requesting an **Audit**.

Auditee:
Organisation being audited.

Auditor:
Person with the **competence** to conduct an **Audit**.

TERMS AND DEFINITIONS (Continued)

Audit Team:
One or more **Auditors** conducting an **Audit**.

Technical Expert:
<Audit> person who provides specific knowledge of or expertise on the subject to be audited.

Competence:
Demonstrated ability to apply knowledge and skills.

TERMS RELATED TO QUALITY ASSURANCE FOR MEASUREMENT PROCESSES

Measurement Control System:
Set of interrelated or interacting elements necessary to achieve **metrological confirmation** and continual control of **measurement processes**.

Measurement Process:
Set of operations to determine the value of a quantity.

Metrological Confirmation:
Set of operations required to ensure that **measuring equipment** conforms to the **requirements** for its intended use.

Measuring Equipment:
Measuring instruments, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realise a **measurement process**.

Metrological Characteristic:
Distinguishing feature that can influence the results of measurements.

Metrological Function:
Function with Organisational responsibility for defining and implementing the **Measurement Control System**.

ISM DEFINITIONS

1. "**International Safety Management (ISM) Code**" means the International Management Code for the Safe Operation of Ships and for Pollution Prevention as adopted by the Organisation by Resolution A.741 (18), as may be amended by the Organisation. Adopted as Chapter IX of SOLAS (Nov 1994)

2. "**Company**" means the Owner of the ship or any other Organisation or person such as the Manager, or the Bareboat Charterer, who has assumed the responsibility for operation of the ship from the Shipowner and who on assuming such responsibility has agreed to take over all the duties and responsibilities imposed by the ISM Code.

3. "**Administration**" means the Government of the State whose Flag the ship is entitled to fly.

4. "**Safety Management System**" means a structure and documented system enabling Company personnel to effectively implement the company Safety and Environmental Protection Policy.

5. "**Document of Compliance**" (DOC) means a document issued to a company that complies with the requirements of the ISM Code.

6. "**Safety Management Certificate**" (SMC) means a document issued to a ship, which signifies that, the Company and its Shipboard Management operates in accordance with the approved Safety Management System (SMS).

7. "**Safety Management Audit**" means a systematic and independent examination to determine whether the SMS activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

8. "**Major Non-Conformity**" means an identifiable deviation that poses a serious threat to personnel or ship safety or serious risk to the environment and requires immediate corrective action. In addition major non-conformity includes lack of effective and systematic implementation of the requirements of the ISM Code.

9. "**Non-Conformity**" means an observed situation where objective evidence indicates the non-fulfilment of a specified requirement.

10. "**Objective Evidence**" means quantitative or qualitative information, records or statements of fact pertaining to safety or to the existence and implementation of a Safety Management System element, which is based on observation, measurement or test and which can be verified.

11. "**Observation**" means a statement of fact made during a Safety Management Audit and substantiated by objective evidence.

PART 3

THE PHILOSOPHY

OF

QUALITY MANAGEMENT

Customer-Supplier Relationship	**3.1**
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Real or Objective Evidence of Quality	**3.3**
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THE PHILOSOPHY OF QUALITY MANAGEMENT

CUSTOMER-SUPPLIER RELATIONSHIP

The background to Quality Management is the relationship between the Organisation and its Customers. The purpose of any Quality System is to ensure complete satisfaction by the Customer with the goods or services provided by the Organisation, however ISO9001:2000 looks for the enhancement of Customer satisfaction. This, in turn, implies an active rather than a passive relationship. The cornerstone then is to first fully understand the requirements of the Customer and so this must be determined in the first instance. Depending on the nature of the product or service, either the Customer will, or should, provide a full specification of requirements, or the Organisation, by Market Research and feedback from the market-place, will produce goods to a presumed Customer requirement. Any Quality System must, therefore, involve the Customer, either directly or indirectly. Although this Customer-Organisation relationship may be regarded, at least partly, as external to the Supplier's activities, much the same philosophy applies internally within a Supplier's work-place at each stage of the operation. The Customer may be regarded as the next stage in the process and so a Quality System applies throughout the whole complex of activities.

Often in the past, the quality level of an item was defined more by the experience of a Organisation than by any specific requirements of a Customer. The Customer stated his need in broad terms and the Organisation manufactured an item which he considered filled that need. It was only when the item was complete that it was determined whether or not it suited the Customer's requirements.

Although that was many years ago, these practices did, to a certain extent, spill over into modern industry, the only improvements being that very basic objectives were conveyed verbally or framed into very sketchy fabrication procedures.

The Inspector, who usually worked for and reported to the Production Department, had little idea of the full inspections required as insufficient data was given, due to inadequate information from the Customer and lack of interface with the Design or Engineering Department.

Many inspection results were accepted by the Customer purely on the basis of his/her confidence in the Manufacturer. However, the Customer sometimes gave himself a little added assurance by having a Representative at the Manufacturer's works to witness some of the inspection and test points.

Sometimes defects were not discovered until Manufacture was at an advanced stage, often leading to costly repair work and sometimes involving scrapping with the inevitable schedule delays. In spite of frequent inspection, not all defects were detected and this resulted in the in-service failures with which we are all too familiar.

This was the system (or lack of system) largely practised until very recently and it is not surprising that Customers often criticised the poor quality and delivery performance of their Suppliers. This approach has seriously affected the ability to be competitive in overseas markets.

THE SYSTEMATIC APPROACH

During recent years with design, manufacture and installation processes becoming increasingly complex and safety and environmental requirements becoming more stringent, the old inspection practices have been found to leave too many areas open to human error, notwithstanding the quality and extent of inspection coverage.

Unfortunately, there is still the tendency to cling to these old inspection practices, which serve only to identify that an item or service is acceptable or unacceptable on a ‘go/no-go’-go' basis. Instead one should now be looking at methods which reduce the amount of inspection and testing activities. Everyone in an Organisation should be responsible for the quality of the work they produce rather than relying on the activities of others subsequently to discover any faults. The results of these old inspection practices leave much to be desired.

The philosophy now is to insist on objective or real evidence of quality rather than make an assumption by inspection, or accept a guarantee by a Contractor or Supplier that the required quality does exist.

This real evidence of quality must be seen to exist, not only in the completed product or service but in all activities which are involved in completing that item or service - administration, design, procurement, manufacture and installation. By controlling all those functions in a systematic manner one can be reasonably assured that each activity is right before the next activity commences. This could be construed as the Producer/Receiver relationship, with each function being responsible for the quality of its own product, i.e. the results of one’s own endeavours.

However, the evidence of quality discussed so far relates to all the activities concerned with the actual design, procurement, manufacture and installation of an item or the production of a service. These activities in themselves, if they are under control, will give the Customer the product in a 'fit for purpose' condition and within budget and on schedule. There are many other functions outside these areas which indirectly affect the efficiency of achieving fitness for purpose. These include such functions as: Market Research, Sales, Finance, Administration and Maintenance, and should all be included in the total Quality Assurance System. Thus we would not only achieve fitness for purpose but it would be achieved in the most efficient and cost-effective manner. Inevitably such increase in efficiency must lead to increased profitability with all its attendant benefits.

REAL OR OBJECTIVE EVIDENCE OF QUALITY

This is the evidence which confirms that all activities within each of the functions of a manufacturing or a service process and, in the case of large projects, site construction and commissioning, have been carried out in accordance with established working methods. These methods are identified in documents, which are known as Procedures and Job Instructions.

Procedures will detail the purpose and scope of an activity and will also identify how, when, where and by whom the activity is to be carried out. Emanating from such will be documents which will detail the results of these activities. A Design Process, for example, will produce a document such as a Specification, a Drawing or a Data Sheet. A Procurement Process will produce a document such as a Tender Package, Purchase Order or Contract. An Inspection or Test Process will produce a document such as a Mill Certificate, Non-destructive Testing Certificate or Heat Treatment Certificate.

Job instructions will direct personnel in a specific task. In the main, Job Instructions do not produce documentation and can be audited only by watching the person involved carry out the task.

It is these procedures, together with the documentation, which give the objective evidence of quality.

Review of International Standards

All International Standards are reviewed at least once every five years by the responsible TCs/SCs. In this review process a majority of P-members of the TC/SC involved decide whether an International Standard should be:

- confirmed,
- revised or;
- withdrawn.

Background to the development stages of the ISO 9000 Series

Under ISO protocols all International Standards are required to be reviewed every five years to determine if they should be confirmed, revised or withdrawn. To this end in 1990, ISO/TC 176 adopted a two-phase revision process to the then current 1987 version of the ISO 9000 series;

- the first to allow limited changes which was completed in 1994;

- the second, reaffirmed in 1996, and a more thorough revision, is now complete and is now known as the 2000 revision of the Standards.

3.4

The remit to the technical committee when reviewing the 1994 version of the standard was to ***minimise the impact of the review on those organisations already certified.***

For this second stage of revision it was decided to adopt a project management approach to the development of the standard and this resulted in a project plan with four main elements:

1. An analysis of customer needs
2. The development and verification of a new draft standard
3. The validation of the new draft standard
4. The Introduction of the new standard together with product support programmes.

An extensive global survey of ISO 9000 series users and customers was undertaken. From the responses received, which were from the majority of those initially circulated, the indications were organisations wanted to see the following embraced within the revised ISO 9000 family of standards.

- The adoption of a process approach
- Compatibility with other management system standards
- The additional requirement for continual improvement
- Recognition of the needs of stakeholders
- The need to be user friendly.

As many delegates will know, there are some twenty standards in the ISO 9000 family and this has caused some concern and confusion. The eventual objective therefore is that there will be four core standards:

1. ISO 9000 Concepts and terminology
2. ISO 9001 Requirements for quality management
3. ISO 9004 Guidance for Performance Improvement
4. ISO 19011 Guidelines on quality and environmental auditing

The various meetings of the TC's and SC's resulted in advancing ISO 9000:2000, ISO 9001:2000, ISO 9004:2000 to formal issue on the 15th December 2000.

3.5

OVERVIEW OF THE NEW STANDARD – ISO 9001

The first look at the new International Standard clearly conveys that the structure has changed considerably comparing with the second (1994) edition; the familiar layout of the requirements of twenty system elements (4.1 – 4.20) has disappeared and the process focused approach has replaced it.

This is represented in the model given below:

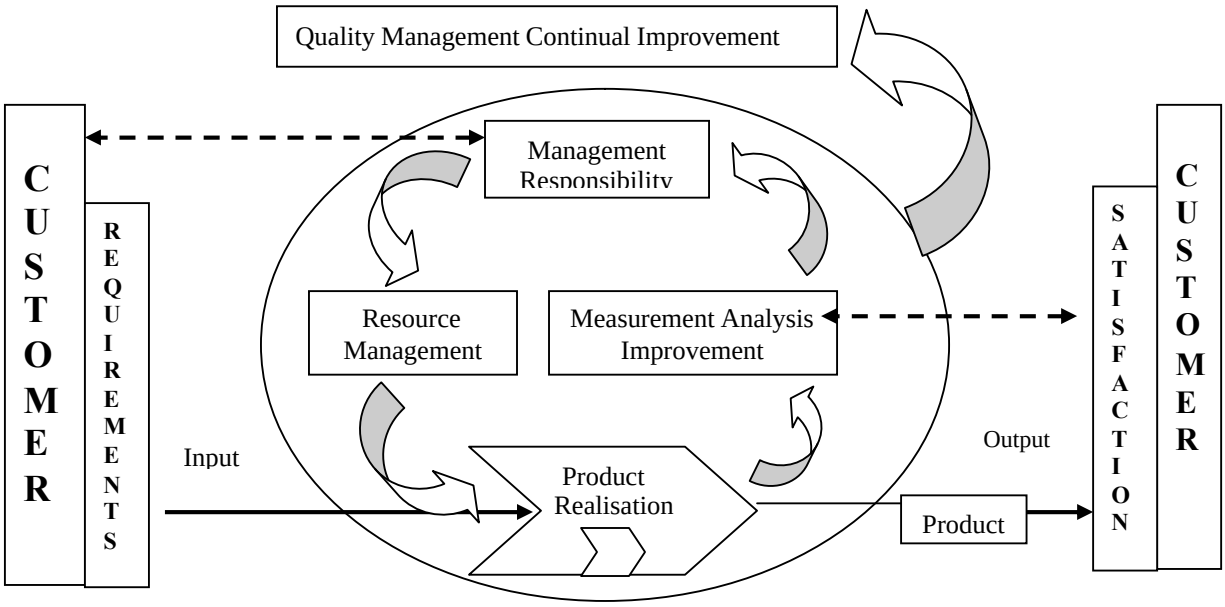

Figure 1 Conceptual Presentation of the 2000 QMS Model

The model illustrated in Figure 1 represents conceptual presentation of the Quality Management System requirements stipulated in the Standard. It reflects the integration of four major headings (Clauses 5, 6, 7 and 8) of the new Standard and shows how the processes interact to form the integral structure of a Quality Management System.

Figure 1 does not intend to illustrate the processes of the Quality Management Systems in a detailed manner. Instead it presents a generic model demonstrating the interaction between the processes.

One loop (vertical) illustrates interrelation between Management responsibility (Clause 5), which creates the system framework, determination and application of resources within Resource Management (Clause 6) needed to exercise product realisation processes (Clause 7) in order to transform Customer's needs and expectations into defined requirements, which if met will allow achieving Customer's satisfaction. The loop is completed by measurement, analysis and improvement (Clause 8), which provides a feedback to Management Review (Clause 5.6) so the cycle returns to Management responsibility (Clause 5) which includes authorisation of changes and initiation of improvement.

The other (horizontal) loop illustrates the significance of the role of Customers and other interested parties. This role is not limited to providing the input requirements. Customers and other parties feedback is essential for identifying the need and potential for further improvement. The process for measurement of Customer satisfaction (Clause 8.2) therefore completes the horizontal loop.

Both loops are clearly based on the familiar principle of Deming's Wheel:

Plan – **D**o – **C**heck – **A**ct:

and both loops generate feedback for the continual improvement process.

The Standard is now structured in the following sections, as clearly indicated in the Fig 1.

Foreword

0 Introduction
1 Scope
2 Normative Reference
3 Terms and Definitions
4 Quality Management System Requirements
5 Management Responsibility
6 Resource Management
7 Product and/or Service Realisation
8 Measurement, Analysis and Improvement

(Sections 4-8 contain the existing 1994: 4.1 - 4.20, together with additional requirements.)

The revised ISO 9000 family of Standards strongly encourages the adoption of this ***Process Approach*** to the Management of an Organisation as a means of identifying and using the opportunities for improvement throughout the Organisation.

THE ROLES OF 9000, 9001 AND 9004

It is worth noticing that the new Standards of ISO 9001 and ISO 9004 are intended to form a **consistent pair** of Standards, which can be used together or as stand-alone documents. It should be understood that ISO 9004:2000 is **not** intended to be a guide for implementation of ISO 9001.

ISO 9004 **is** meant to lead beyond the requirements of ISO 9001 and guide the Organisations towards a more comprehensive approach to Quality Management and performance improvement. Indeed whereas ISO 9001:2000 looks at effectiveness of the Quality Management System, ISO 9004:2000 is concerned with its efficiency. Whilst ISO 9004:2000 is not intended as an implementation guidance, it is intended to be a guide to Top Management who wish to move beyond the requirements of 9001:2000. ISO 9004 contains the requirements of ISO 9001:2000 cited within the text boxes for easy reference.

Both ISO 9001 and ISO 9004:2000 embrace the eight (8) principles of Quality Management, which are:

1. **The Customer Focused Organisation**
   Organisations depend on their Customers, and therefore need to identify and understand their present and future needs in order to be able to meet the Customers' requirements and, indeed, to strive to exceed them;
2. **Leadership**
   Management is not an administration activity; leadership is needed to provide unity of purpose, direction and to create an environment in which people in the Organisation become fully involved in achieving the Organisation's objectives;
3. **Involvement of People**
   Peoples' co-operation and involvement allows for their abilities to be fully and effectively used for the Organisation's benefit;
4. **Process Approach**
   For the results to be achieved efficiently the resources and activities need to be managed as processes;
5. **System Approach to Management**
   Identifying, understanding and managing a system of interrelated processes for achieving objectives contributes to effectiveness and efficiency of the Organisation;
6. **Continual Improvement**
   Is a permanent objective of an Organisation;
7. **Factual Approach to Decision Making**
   Effective decisions are based on the logical and intuitive analysis of data and factual information;
8. **Mutually Beneficial Supplier Relationship**
   Such a relation between the Organisation and its Suppliers will enhance the ability of both Organisations to create value.

THE NEED FOR AUDIT

Having then established a system to cover all activities and functions of a Company, how can it be ensured that all these procedures are being properly adhered to? What takes the place of inspection in the old system of operation? The answer is a Conformance Audit.

What is an Audit expected to prove?

An Audit is undertaken to indicate whether a system, procedure or job instruction is working satisfactorily. It readily highlights non-conformances and should lead to action being taken to correct them and to identify the root cause and to prevent their recurrence. The requirements for Quality Assurance Audits are determined by Management and, as such, Management responsibilities should be integrated into the Quality Assurance System.

Therefore it is a Management decision to implement Audits and, in order for an Audit to work effectively, the group concerned with implementing Audits must have the organisational freedom to oversee the development, implementation and maintenance of the Quality System. In this context, the word 'Group' can imply as few as one or even a part-time activity, depending on the size and nature of the Company.

For the sake of convenience, this group is usually given the title 'Quality Assurance Department'. This is perhaps unfortunate as Quality Assurance is a philosophy which should be practised throughout an entire Organisation and should not be regarded as the responsibility of just one department.

To secure the required Authority, organisational freedom and independence, it is essential, therefore, for the Quality Assurance Representative to report directly to Senior Management. The ISO Quality System Standards actually refer to the Quality Assurance Manager as the Management Representative' thus emphasising the importance of the position. This is the *sine qua non* of any effective Quality System. Any attempt to place the so-called Quality Assurance Department within, say, the Production Department, indicates that Management has not appreciated the philosophy of Quality Assurance.

In most cases where Quality Assurance has been ineffective this has been due, in the main, to an incorrect 'Chain of Command'.

THE NEED FOR PROCEDURES

In order to assess and report any procedural non-conformances within any discipline or department and to obtain positive corrective action, it is imperative that all personnel with a Quality Assurance function are adequately qualified and experienced and are accepted and respected as such. The personnel involved should not be regarded as a policeman but as a guide, philosopher and friend!

To implement a Quality System and to assess and report shortcomings within the system, the Quality Assurance Department must have bases upon which to work. These bases are in many cases the written procedures which should indicate 'what' is required or is to be controlled; 'who' is responsible for ensuring the requirement is met or the control carried out; and 'how', 'when', 'where' and possibly 'why' it is controlled. In addition, the procedures will describe how quality and safety requirements will be accounted for.

As well as taking account of quality requirements, it is also important that procedures indicate how interface problems between departments or disciplines can be avoided. The procedures which involve an interface between departments or disciplines must, therefore, have the approval of all those groups directly concerned. A procedure should be written by the main discipline or department concerned, in consultation with the Quality Assurance Department, to ensure that all relevant quality requirements are included and that the document is capable of being audited.

ADVANTAGES OF A QUALITY MANAGEMENT SYSTEM

1. The ISO series of standards has global recognition

2. ISO certification provides objective Third Party Assessment

3. A Certified Quality Management System eliminates or reduces time consuming, expensive, multiple Audits by prospective customers.

4. The Regulatory Authorities may soon require companies to be Certificated to an Internationally recognised Quality System.

5. Enhances customer satisfaction

6. Opens the way to improvement

7. Provides a valuable management tool for reducing wasteful effort and evaluating efficiency.

8. Creates smoother operation, increases productivity, improves economic performance.

9. It illustrates a company commitment to superior performance

10. It is good business.

QUALITY MANAGEMENT

THE COST OF

QUALITY NEGLECT

CAN BE BETWEEN

5% - 45%

OF REVENUE

QUALITY MANAGEMENT

EXAMPLES OF QUALITY COSTS

- SCRAP
- COST OF PRODUCING SCRAP
- COST OF STOCKING, INSPECTING, REJECTING AND TROUBLE SHOOTING
- COSTS OF DEALING WITH COMPLAINTS ON SUPPLIER AND TROUBLE SHOOTING SOLUTIONS
- COSTS OF DELAYS TO PROGRAMME
- COST OF CUSTOMER CONFIDENCE
- COST OF DEALING WITH CUSTOMER COMPLAINTS AND RESUPPLY
- INTEREST ON PAYMENTS RETAINED THROUGH DEFECTIVE PRODUCT/SERVICE
- INTEREST ON INCORRECTLY INVOICED SERVICES
- INTEREST ON INADEQUATELY CONTROLLED DEBTORS
- COST OF DEMOTIVATED STAFF

THE MAIN QUALITY FAILURES

1. INSUFFICIENT PLANNING

2. INSUFFICIENT TRAINING

3. NO SYSTEM FOR MONITORING

4. INEFFECTIVE DOCUMENTATION CONTROL

5. INSUFFUCIENT RESOURCES

6. POOR MEASUREMENT

MANAGEMENT AUDITS REVEAL

- INTER-DEPARTMENTAL RESPONSIBILITIES BLURRED
- PROCEDURES TOLERATED BUT GENERALLY IGNORED
- FEEDBACK INADEQUATE (Faults being more easily corrected at the workplace than reported)
- COMMUNICATIONS DEFICIENT

MANAGEMENT AUDITS REVEAL

- 80% OF PROBLEMS ARE OWNED BY MANAGEMENT

- 20% ARE OWNED BY THE WORKFORCE

WHY CUSTOMERS QUIT

- 1% DIE
- 3% MOVE AWAY
- 5% HAVE OTHER FRIENDS IN THE BUSINESS
- 15% QUIT FOR COMPETITIVE REASONS SUCH AS PRICE
- 18% QUIT BECAUSE OF PRODUCT DISSATISFACTION
- 58% QUIT BECAUSE OF THE ATTITUDE AND INDIFFERENCE OF AN EMPLOYEE

PART 4

DEVELOPING

THE APPROPRIATE

QUALITY MANAGEMENT SYSTEM

The Responsibility for Quality	**4.1**
First Considerations	**4.1**
Public Relations	**4.3**
The Cost of Quality	**4.4**
The Process Approach	**4.4**
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DEVELOPING THE APPROPRIATE QUALITY MANAGEMENT SYSTEM

THE RESPONSIBILITY FOR QUALITY

The Senior Executive of any Organisation is responsible for two things: the efficiency of the Company, and the quality of the goods or services, which that Company offers.

In the larger Organisation he/she will ultimately be responsible to the Shareholders for the efficient running of the Company and its profitability.

In the smaller Organisation, where the Senior Executive may well be the Owner of the Company, he/she will have a responsibility to the Company's Employees, to one's own family and, in all probability, to the Bank Manager for the viability of the Company.

FIRST CONSIDERATIONS

Any Organisation, large or small, whether privately owned or not, can remain viable only if it continues to produce items or services which the Customer wants and at a price the Customer is prepared to pay. There are, therefore, two things that must first be considered when embarking on a Quality Management System.

There is first the need to satisfy and enhance Customer requirements by producing items or services which are fit for the purpose, within budget and on schedule, and secondly the need to supply these items or services in the most efficient and cost-effective manner. These can be accomplished only by introducing effective Management Quality Systems.

The Need To Satisfy Customer Requirements

This can be achieved by developing and implementing a Quality System utilising the criteria given in the appropriate general Quality System Standard, such as the ISO 9001:2000. The requirement to implement a Quality System to an industry-related Quality System Standard will, no doubt, have already been demanded by the Purchasing Body for that industry and may be a Contractual obligation. There are, however, many instances where Customers, other than those in safety-related industries, are demanding conformance with an appropriate Quality System Standard.

In any event, there are difficulties in meeting imposed requirements, as most Quality System Standards are open to interpretation and misinterpretation. It is, therefore, recommended that, initially at least, any Company embarking upon a Quality Management System should use the available Quality System Standards as guidance documents only. Indeed, it may well be prudent to develop the Quality System independently of the Quality System Standards, verify its implementation and effectiveness by Audit and then determine with which Standard the system complies.

The Purpose of an Organisation is:

- To identify and meet the needs and expectations of its Customers and other interested parties (people in the Organisation, Suppliers, Owners, Society), to achieve competitive advantage and to do this in an effective and efficient manner **and**

- To achieve, maintain and improve overall organisational performance and capabilities.

The application of Quality Management principles not only provides direct benefits but also makes an important contribution to managing costs and risks. Benefit, Cost and Risk Management considerations are important for the Organisation, its Customers and other interested parties. These considerations on overall performance of the Organisation may impact:

- Customer loyalty.

- Repeat business and referral.

- Operational results, such as: Revenue and Market share.

- Flexible and fast responses to market opportunities.

- Costs and cycle times through effective and efficient use of resources.

- Alignment of processes that will best achieve desired results.

- Competitive advantage through improved organisational capabilities.

- Understanding and motivation of people towards the Organisation's goals and objectives, as well as participation in continual improvement.

- Confidence of interested parties in the effectiveness and efficiency of the Organisation, as demonstrated by the financial and social benefits from the Organisation's performance, product life cycle and reputation.

- Ability to create value for both the Organisation and its Suppliers by optimisation of costs and resources as well as flexibility and speed of joint responses to changing markets.

PUBLIC RELATIONS

In the widest sense, Quality Management should apply to the whole business activity - the total presentation - and not just to the product or service. In particular, this applies to what is nowadays called 'Public Relations' or 'PR'. Just as most Management Systems are applied common sense, most PR is, in reality, just old-fashioned courtesy and 'good manners'. It is an area in which all too many 'Quality-conscious' Organisations fail. The items they produce or the services they give can be of the highest quality yet, for example, if that Organisation neglects to keep the Customer informed of delays due to unforeseen circumstances, then that Customer becomes agitated and with good reason. He/she expects to be informed of the reason for the delay; common courtesy demands it. Communication is of the utmost importance. Keep the Customer informed and it is realised that the Company has the Customer's interests at heart.

Management should also appreciate - but all too rarely does - that perhaps a Company's most important members of staff are the Receptionist and Switchboard Operator - the links with the outside world. It is frustrating, and all too common, to be connected to an extension, via a switchboard, and to find that the extension remains unanswered and the caller left 'high and dry'. In such circumstances, the Operator should be instructed to intercept the call and offer an alternative connection. This practice is carried out all too infrequently by many large and reputable Organisations and is compounded by the use of automatic switchboard systems.

The Reception Area is another case in point. There are many instances on record where a visitor to a Company is kept waiting, or worse ignored, while the Receptionist finishes a private telephone conversation or is engaged in idle conversation with a Colleague. Similarly, keeping a caller waiting is bad manners. First impressions are extremely important and creating the right 'image' is essential it is the first step to ensuring a good, long lasting working relationship with the Customer.

Such malpractice can have only an adverse effect on the overall business efficiency of an Organisation and the elimination of them should, therefore, be included in any plan designed to increase the effectiveness, profitability and competitiveness of a Company. A Company must always be regarded as 'good to deal with'.

THE COST OF QUALITY

All Companies employ someone to be responsible for the accuracy of its financial transactions and, in the main, that person occupies an Executive post. That person is usually aware of the cost associated with such matters as absenteeism, holidays and down-time, and the Senior Executive will be obliged to present a complete Financial Statement to the Authorities and, where necessary, to the Company's Shareholders. It is only rarely that a Company will employ an Executive who is responsible for quality yet, in many instances, a Company's quality costs can be equal to, or even exceed, the profit margin of that Company. Quality costs are generally not totally recognised.

A Company will, in all probability, keep quite detailed records of goods returned under guarantee but will rarely be able to identify the costs related to returning, reworking substandard items, revising design drawings and specifications, repairing faulty structures due to poor workmanship and others. Quality costs are the cost of putting things right! When an analysis is made of all associated costs, the result can be quite substantial. It should, therefore, be a requirement of every Senior Executive to realise what these costs are. The requirement to keep a detailed analysis of a Company's financial affairs is required by Legislation and yet, where the costs associated with putting things right are concerned, this is usually given scant attention.

In most Manufacturing Organisations there is a department, which is given the responsibility for quality, and, as has already been stated, this department is given a variety of titles all bearing the word *'Quality'*. In many instances, as we have seen, this department although responsible for the control of the quality of the manufactured item, has no responsibility for verifying that all activities which preceded the manufacturing or process function were correct.

Companies should look towards the total integration and control of all activities. This cannot be achieved by the department responsible solely for quality control or inspection, as the result will be only an increased activity in inspection and/or testing, which, in turn, increases the costs of putting things right.

THE PROCESS APPROACH

The Third Edition of ISO 9001 strongly encourages the 'Process Approach' to Quality Management.

The Process Approach facilitates an Organisation's ability to identify and understand its activities, their interdependencies and their capabilities. This enables an Organisation to define and control these activities.

4.5

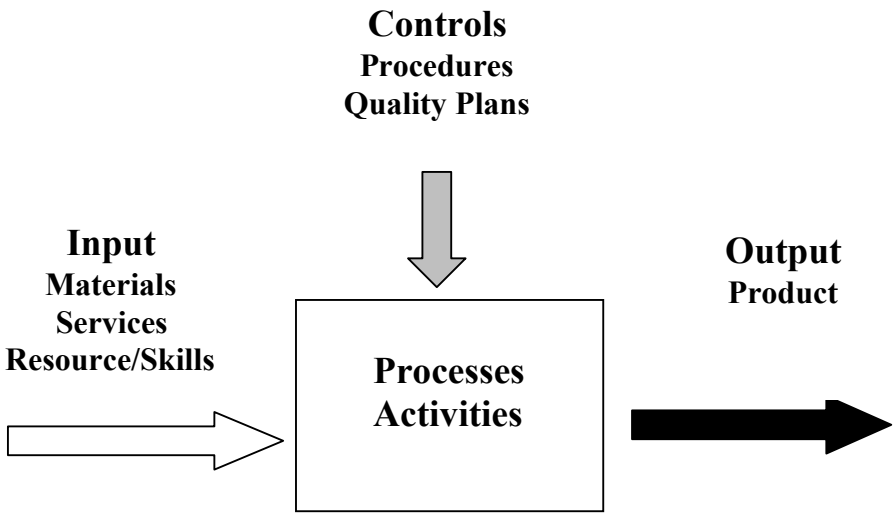


Figure 1 Concept of the Process

It should be understood that every Company is unique and that the input, the control and/or the output can be tangible or intangible. Processes can be combined in a network that collectively achieve a planned purpose. Figure 2 shows an example of such a network.

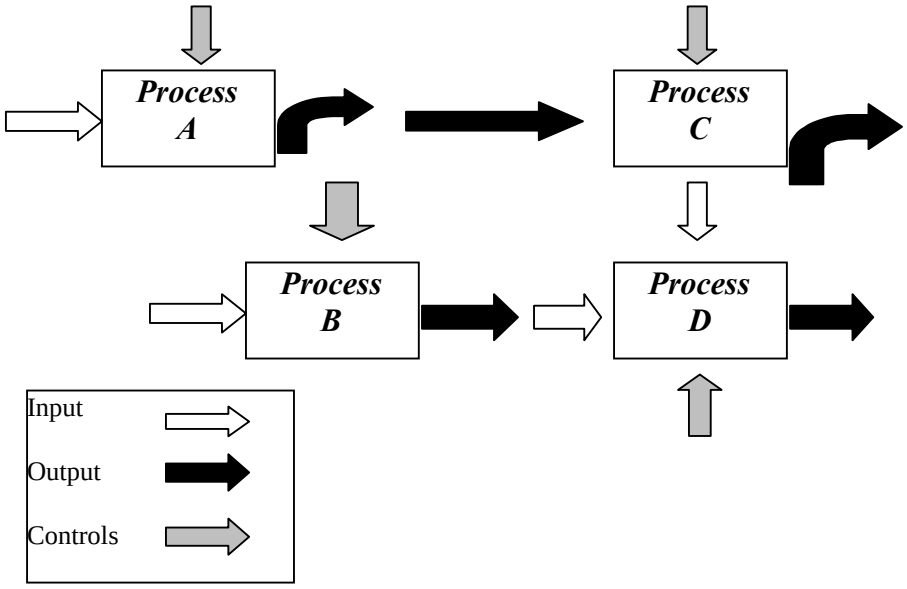


Figure 2: Sequence and Interactions between Processes

It can be seen that an output from one process can be an input to another process. In this way, processes can be combined in a process chain. In an effective Quality Management System, processes and the associated responsibilities, procedures and resources are established and maintained in a consistent and logical/efficient manner. The Quality Management System requires co-ordination and compatibility of its processes, and definition of their interfaces. This essentially establishes the concept of every function/department having:

- Internal Suppliers.
- Internal Customers.

It is necessary when developing and implementing a Quality Management System to appoint, preferably in an Executive position, a person who is to be responsible for co-ordinating and monitoring the system. The appointed person should have Management capabilities and will be expected to be the Guide, Philosopher and Friend mentioned earlier.

It is also essential for this person to be able to communicate at all levels. Knowledge and experience of the industry are essential requirements, as are the understanding and application of Management Systems. A knowledge of efficiency techniques would be an added advantage. This person, once appointed, would in effect represent the Senior Executive and would determine, with other Management Representatives, the functions to be controlled to achieve the required fitness for purpose.

ACHIEVING ACCEPTANCE OF THE QUALITY MANAGEMENT SYSTEM

As we have seen, an effective Quality Management System involves all departments and functions. Such a system can be developed only with the full participation and co-operation of all concerned, who must have the opportunity of helping to shape the system. A system that has been thoroughly discussed and agreed is much more likely to be accepted and implemented than one that is imposed - whoever does the imposing! It is worthwhile expending a great deal of effort in obtaining this co-operation and acceptance. It is necessary, therefore, for the respective department and/or discipline heads to be involved in determining the applicable system level. This can be achieved, in the first instance, by forming a Working Party, which should comprise Representatives from all the departments and/or disciplines concerned.

SETTING UP THE WORKING PARTY

The responsibility for the formation of the Working Party should lie with the person who has been appointed to the Quality Executive Position.

It is essential that the person who operates in the Quality Management Position represents the Senior Executive of the Organisation and that he or she has independence of action. All Quality Assurance Standards, regardless of country of origin, place great emphasis on this point and, in general, the criterion is that the person so appointed should preferably be independent of all other functions.

In the case of large Organisations, this independence is comparatively easy to achieve and the Quality Assurance Department will operate as a totally autonomous group but, with the small Organisations, it is not possible to achieve this independence economically and it is in such instances that the **function** rather than the **person** should be defined.

The Working Party should be chaired by the Senior Executive of the Organisation, with the Quality Management Executive acting as the Co-ordinator. This Working Party should include Representatives from all the major departments and/or disciplines and these Representatives should be, preferably, Heads of Departments and/or disciplines. Where this is not possible, then the Representative should be given Power of Attorney to act for the respective Head.

DOCUMENTS AND RECORDS

Documents

Documents are produced detailing how the system is to be implemented and these could well start with the POLICY MANUAL, leading on to the PROCEDURES MANUAL and amplified in WORK INSTRUCTIONS. A competent authority prior to being published for implementation will approve all these documents.

Records

Records are produced to confirm that procedures and/or work instructions conform to the laid down documentation and provide an auditor with objective evidence that procedures are being followed. A list of records is normally maintained in order to monitor the progress of the system.

ESTABLISHING THE APPROPRIATE QUALITY MANAGEMENT SYSTEM

The objective of the Working Party is to establish the appropriate Quality Management System applicable to the Organisation concerned. Before this can be done, experience has shown that it is usually necessary for certain actions to be taken, such as:

- To define responsibilities and lines of communication within each department or discipline.
- To establish inter-departmental interfaces.
- To verify and agree the activities and functions which are to be controlled.
- To communicate to all Employees the reasons for, and the benefits to be obtained from, the implementation of a Quality Management System.

TAKING EACH IN TURN:

Define responsibilities and lines of communication within each department or discipline

In many Organisations a person's responsibilities are not clearly defined. There is a tendency to appoint someone to a given position and then to delegate additional responsibilities to that person as he or she becomes more proficient and experienced. As time goes on, this person reaches Supervisory or Management status purely by taking on these additional responsibilities and then, when things go wrong, it becomes exceedingly difficult to identify the cause or the source of the problem.

All responsibilities should be documented in the form of job descriptions, which should include as a minimum:

1. The title or description of the position.
2. The grade or level of the position.
3. The reporting structure of the position.
4. Whether or not the position carries any Supervisory responsibilities.
5. The primary responsibilities of that position.
6. The knowledge and experience required to fill that position.

Once job descriptions have been documented then it will be possible to formulate Organisation Charts for each of the departments concerned. These Charts will enable each grade, or level of Employee, to understand and accept where their position is located within the hierarchy and to whom each person reports.

Establish Interdepartmental Interfaces

Organisation Charts can be established for individual departments and/or disciplines but they will not achieve the integration of the total system if they are developed in isolation. No department can work in isolation. There is always the need to liaise with others. For example, Sales must liaise with Design, Production and Finance. An Organisation Chart, which identifies these interfaces, should, therefore, be developed. Where interfaces are established, then of course these would be documented in the appropriate job descriptions and procedures.

This detailed Organisation Chart will ultimately identify the primary positions and reporting routes of the Company.

Verify and agree the activities and functions that are to be controlled

This activity will eventually determine the appropriate Quality System level and this is where the Standards themselves give useful guidance.

The total activities, or major activities, of the Organisation should first be listed. If a Company is engaged in the design, manufacture and installation of a product, then each activity within each of these three elements should be itemised.

For example, the control of design would cover such activities as:

- Establishing design parameters.
- Detailing the design.
- Design checking.
- Design approval.
- Control of design changes.
- Development of specifications, and others.

The control of manufacture would cover such activities as:

- Incoming inspection.
- In-process inspection.
- Non-destructive testing.
- Final inspection, and others.

PERMISSIBLE EXCLUSIONS

Under ISO 9001:2000 it is allowed to exclude certain Quality System requirements for processes which are not performed or required in view of Customer or Regulatory requirements, or due to the nature of the product or service.

Conformance is, of course, required for the remaining elements of the Standard. Exclusion of a requirement must not affect the Organisations ability to meet the requirements and does not absolve the Organisation from the responsibility of providing conforming product/service.

It is also important to note that any exclusion must be limited to the requirements contained in Clause 7 of the Standard "Product Realisation".

Auditor Note – Permissible Exclusions

If permissible exclusions against Clause 7 requirements are referred within the Company's Quality Manual and Auditor/Audit Team should identify this as an area for verification during the on-site Audit to ensure that the Company have not – either inadvertently or deliberately – misused this ISO Statement. The most likely areas for Company's to claim "Permissible Exclusions" are:

- Design and Development (7.3.) – Where the Organisation has no responsibility for the design and development of the PRODUCT it provides.

- Identification and Traceability (7.5.3.) – this Clause could only be partially applicable where there is no specific traceability requirement for the Organisation's product.

- Customer Property (7.5.4.) – Where the Organisation uses no Customer property in its product or product realisation processes. Note that if the Customer provides a proprietary design for the product, this may constitute intellectual property and must be covered by the Organisations QMS.

- Control of Monitoring and Measuring Devices (7.6.) – Where the Organisation needs no monitoring and measuring devices to provide evidence of the conformity of its product. This may be the case for some Service Organisations, among others.

Auditor Note – Exclusions Not Permitted

If an Organisation excludes from its QMS ISO 9001:2000 requirements that do not meet the criteria established in 1.2 then conformity to ISO 9001:2000 may not be claimed or implied.

This includes the following situations:

- Where an Organisation fails to comply with the requirements of 4.2.2. (a) – Quality Planning – to provide justification for exclusion of specific Clause 7 requirements.

- Where an Organisation decides not to apply a requirement in Clause 7 based only on the justification that this was not a requirement of either ISO 9001/2/3:1994 and has not been included in the Organisation's existing QMS.

- Where requirements in Clause 7 have been excluded because they are not required by Regulatory Bodies but where this requirement affects the Organisation's ability to meet Customer requirements.

- Where a Customer specific contractual statement specifies that a requirement covered by Clause 4,5,6,8 of ISO 9001:2000 is not required by that particular Customer.

DOCUMENTING THE QUALITY MANAGEMENT SYSTEM

When all the major activities have been identified, then a brief outline describing what is done to control these activities can be documented. These outlines assist in determining the procedural requirements and they will also be utilised in the formation of the Quality Management Manual.

A Quality Manual is a requirement of IS0 9000. The Quality Manual includes or references the documented procedures that form part of the Quality System. Guidance on Quality Manuals is given in ISO 10013. Documented procedures may be developed to control the various processes within an Organisation.

It will be seen that a number of 'levels' or 'tiers' of documentation are being developed and these are:

- The Quality Manual.
- Procedures.
- Job Instructions.
- Forms and Records

These 'tiers' of documentation are shown in Figure 4A. **(See 4.14)**

Application to the Service Industry

With this, the Third Version of the ISO 9000 Series being published, one of the most notable changes is its move away from terminology compatible with manufacturing to a far user-friendlier format. As a result application for the Service Industries is a far more straightforward affair, with many of the ambiguities removed.

ISO 9000:2000 Series is applicable to all sectors of Industry and Public Bodies, regardless of size or activity.

A Numbering System should be developed which will identify the procedure to the department that implements it. Such procedures should not be annotated as Quality Management documents.

A typical numbering system would be as follows:

XYZ-DE-001

Where **XYZ** represents the Company's initials, **DE** represents the Design and Engineering Department and **001** represents the document number.

The title of the document would also be indicated, for example:

XYZ-DE-001 Design Validation

Procedures, which are to be implemented by more than one department, are normally of an administrative nature and could, therefore, be identified as:

XYZ-ADM-001 and so on.

Once an index has been developed, it should be kept updated. If it is found that a particular procedure is no longer relevant and can be discontinued, then the number allocated to that procedure should be declared obsolete and not used again, the procedure index being annotated accordingly.

Once the system element outlines and the procedures index have been developed, then it will be possible to identify responsibilities for the authorship of procedures.

The procedure index can be utilised also to identify those procedures, which already exist, and those that have to be written to complete the total system. The exercise of reviewing existing documentation may well highlight the existence of duplicate or similar documents, and possibly documents that are obsolete. This presents a good opportunity for reappraisal and a 'spring cleaning' session.

IMPLEMENTING THE QUALITY MANAGEMENT SYSTEM

The final stage is the implementation of the system. This will involve the co-operation of all concerned and, to obtain this co-operation, all employees must understand the reasons for implementation.

Communicate to all Employees the reason for, and the benefits to be obtained from, the implementation of a Quality Management System

Holding a series of 'Awareness' talks, or Seminars, starting with Senior Management through all levels to junior personnel, best does this. No one should be left out. Co-operation is usually more easily obtained if these 'Awareness' Sessions are conducted before procedural controls are documented but after the Quality Manual has been written and approved. In this way all employees can prepare, and possibly highlight, problem areas that exist because of inadequate controls. By this means, personnel can be made to appreciate that they are part of the system and that it will work to their benefit only if they co-operate.

The 'Awareness' Sessions, then, have the best impact if they are introduced after the Quality Manual has been written and approved. The manual should give Supervisory staff, in particular, the broad outline of the system within the area of their own involvement.

The requirement for review should also be emphasised and this review should include both system and conformance audits. The word 'audit' may frighten some staff as they may expect to be supervised continuously and suspect that Management is adopting the 'Big Brother' attitude. It should be made clear to them that audits are carried out first to verify the adequacy of the system and only secondarily to verify conformance with instructions.

It should also be emphasised that each individual is responsible for the quality of work produced and that reliance for quality cannot be placed on others subsequently to confirm that the required quality standard has been reached. 'Right first time, every time' should be everyone's goal. This is the prime goal of any quality system.

Having reached this stage, it is worthwhile recapping on events so far. All the activities from the appointment of the Quality Executive to the implementation of the system are described in Flow Chart form as Figure 4C.

4.14

Figure 4A - The Four Tiers of Documentation

TIER 1

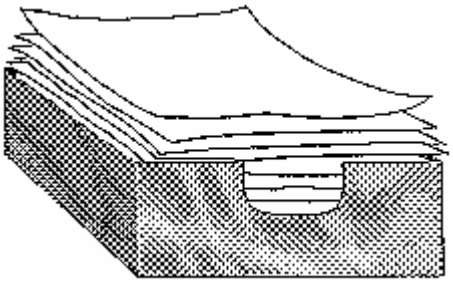
QUALITY MANUAL

TIER 2

PROCEDURES

TIER 3

JOB INSTRUCTIONS



TIER 4

FORMS & RECORDS

4.15
Figure 4B

SYSTEM DOCUMENTATION

THE POLICY MANUAL

DESCRIBES THE QUALITY POLICY, ORGANISATION, PROCEDURES AND PRACTICES OF A COMPANY.

PROCEDURES

DESCRIBE WHAT IS TO BE DONE, AND BY WHOM, AND HOW, WHEN, WHERE AND WHY AN ACTIVITY IS TO BE CARRIED OUT. WILL ALSO DESCRIBE MANAGEMENT INTERFACES AND RESULT IN THE PRODUCTION OF SOME FORM OF DOCUMENTATION.

JOB INSTRUCTIONS

DIRECT A PERSON IN A SINGLE ACTIVITY AND ARE SUBORDINATE DOCUMENTS TO PROCEDURES.

DESIGN BRIEFS

DESCRIBE METHODS OF ACHIEVING THE REQUIRED DESIGN.

COST, TIME AND RESOURCE DOCUMENTS

IDENTIFY THE RESOURCES REQUIRED, THE TIME INVOLVED AND THE COSTS ASSOCIATED WITH A GIVEN ACTIVITY.

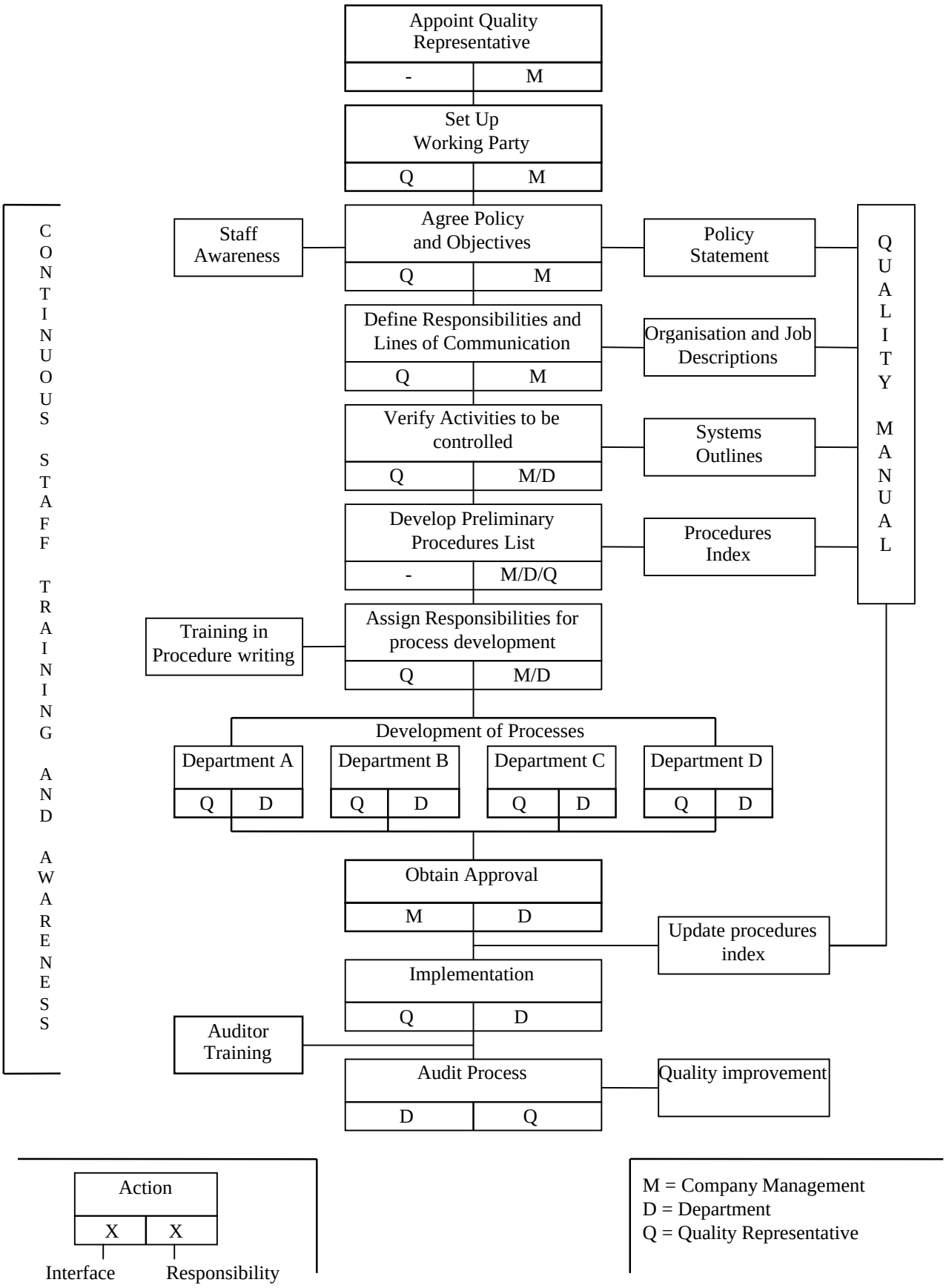
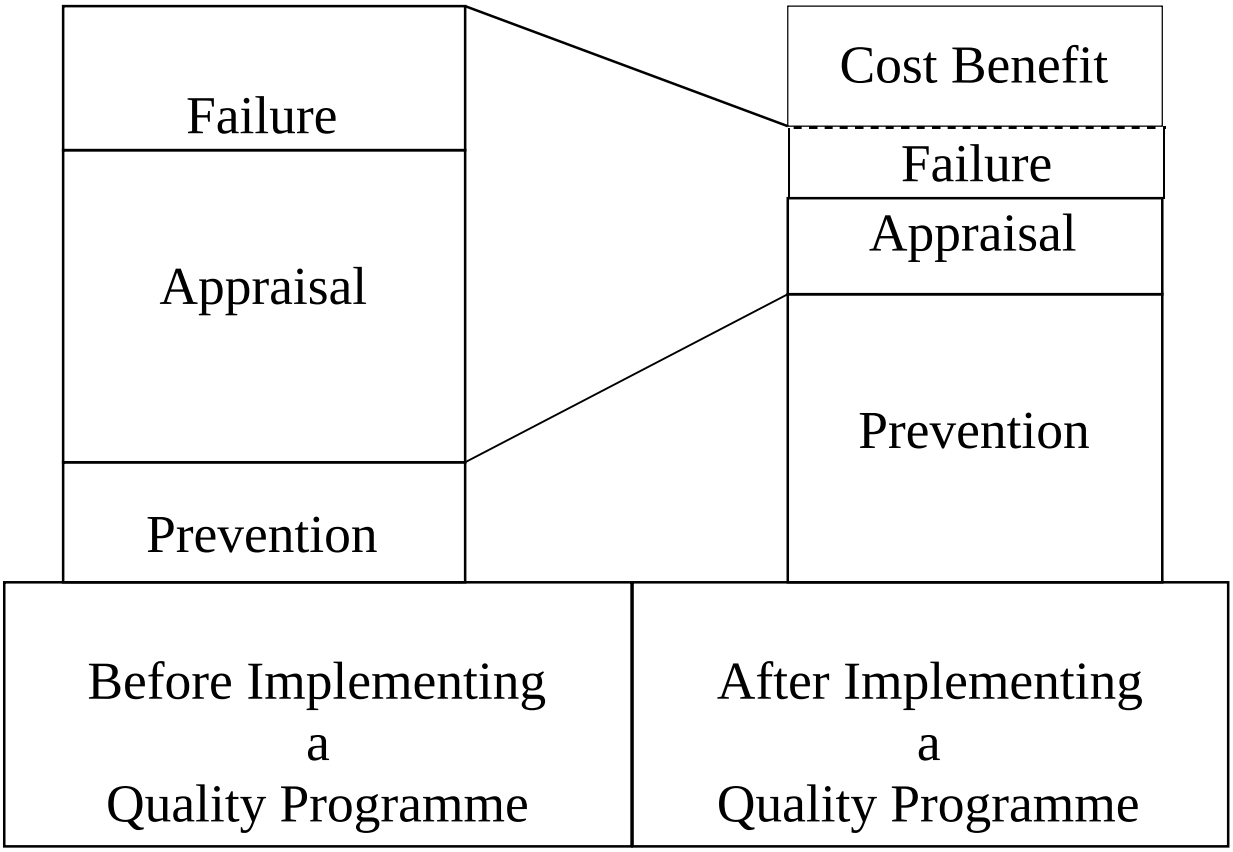


Figure 4C - Quality System Implementation Flow Chart

QUALITY PROGRAMME COST BENEFIT



PART 5

ISO 9001:2000

SYSTEM REQUIREMENTS 1 to 8

Title	**5.1**
Foreward	**5.1**
Introduction	**5.1**
Scope	**5.2**
Normative Reference	**5.3**
Terms and Definitions	**5.4**
Quality Management System	**5.4**
Management Responsibility	**5.6**
Management Review	**5.11**
Resource Management	**5.12**
Production Realisation	**5.14**
Customer Related Processes	**5.15**
Design and Development	**5.17**
Purchasing	**5.20**
Product and Service Provision	**5.21**
Control of Monitoring & Measuring Devices	**5.24**
Measurement, Analysis & Improvement	**5.25**

5.1

GENERAL REQUIREMENTS OF THE STANDARD AND EXPLANATION OF THE REQUIREMENTS FOR MANAGEMENT RESPONSIBILITY, COMMITMENT, CUSTOMER FOCUS, QUALITY POLICY, PLANNING AND ADMINISTRATION

TITLE

ISO 9001:2000 – Quality Management System – Requirements.

FOREWARD

The Foreword advises that the term "Quality Assurance" which was used in previous standards has now been removed from the title and that this is also reflected within the Scope. This reflects the fact that the Standard will not only address the Quality Assurance of product conformity, but also Customer's satisfaction.

INTRODUCTION

General

It states that the Standard presents requirements for a Quality Management System that can be used by an Organisation to address Customer satisfaction, by meeting Customer and **applicable Regulatory** requirements.

The Standard states that its purpose is not to enforce uniformity of Quality Systems. The Standard acknowledges that organisations' Quality Management Systems are structured in many varied forms and that there is no obligation for the organisation to change the structure of their Quality Management Systems and/or the relevant documentation to align with the structure of the Standard.

At the same time the Standard highlights the need for commitment by strongly emphasising that the adoption of the Quality Management System (in accordance with the Standard) needs to be a strategic decision of the Organisation.

Process Approach

The Standard promotes a Process Approach to Quality Management.

The process model, which is illustrated graphically, is a conceptual representation of the Quality Management System requirements specified in the Standard.

Relationship with ISO 9004

It is explained that this Third Edition of the Standard is one of a consistent pair of Quality Management System Standards, the other being ISO 9004:2000, Quality Management Systems – Guidance for Performance Improvement and that they are capable of being used together or as a stand alone document. It is clearly explained that ISO 9004 is not intended to be guidance for implementation of ISO 9001.

Compatibility with other Management System Disciplines

The new Standard starts by reminding us that it has been developed to be compatible with other Standards and that it shares system elements and principles with ISO 14001.

It suggests that common subjects in the two Standards can be integrated, in whole or part, as relevant.

It states that it does not include requirements for other system disciplines e.g. Environment, Occupational Health and Safety or Financial Management, it does however, encourage integration as and when appropriate.

SCOPE

General

The aim of the requirements is clearly explained – that being:

- To demonstrate the ability to consistently provide product that meets Customer and **applicable Regulatory** requirements and

- To address Customer satisfaction through the effective application of the system, including processes for **continual improvement** and the prevention of non-conformance.

A Note explains that the term "Product" applies only to the product intended for, or required by, a Customer.

5.3

Application

It is allowed to exclude certain Quality Management System requirements for the processes where such processes are not performed or required in view of the customer's or regulatory requirements or due to the nature of the product. Conformance with remaining requirements will have to be maintained. Exclusion of the requirements must not affect the organisation's ability to meet the requirements and does not absolve the organisation from the responsibility of providing conforming products.

Any exclusion must be limited to the requirements contained within Clause 7 – "Product Realisation".

NORMATIVE REFERENCE

Users are encouraged to explore the possibility of using latest Editions of referenced Standards. For the dated references, subsequent amendments or revisions of cited Standard do not apply.

Auditor Note – 9000 Definitions

With the emphasis on Continual Improvement, Management Commitment and Customer Focus within the Third Edition of the 9000 Standards the refined definitions and meanings clarified in ISO 9000:2000 should be used to assist in possible areas of misunderstanding in a Company's approach (as well as in an Auditor's approach).

Examples where such 9000 fundamentals and vocabulary can assist are:

1) Top Management
2) Quality Improvement Tools and Techniques

TERMS AND DEFINITIONS

The Standard states:

"For the purpose of the International Standard, the Terms and Definitions given in ISO 9000:2000 – Quality Management Systems – Fundamentals and Vocabulary, apply".

However, two (2) notes are added:

SUPPLIER ———— ORGANISATION ———— CUSTOMER

"Supplier" now replaces the previous term "Sub-contractor"
"Organisation now replaces the previous term "Supplier"
(i.e.: The unit to which the Standard applies)

QUALITY MANAGEMENT SYSTEM

This Clause has the following Sections and Sub-sections:

- **General Requirements**
- **Documentation Requirement:** General
  Quality Manual
  Control of Documents
  Control of Quality Records

General Requirements

In simple terms the Organisation must establish, document, implement, maintain and **continually improve it's Quality Management System** in accordance with the requirements of the Standard.

The Standard goes on by explaining what it takes to establish the system:

- Identify and manage processes necessary for the Quality Management System.
- Determine the sequence and interaction of the processes.
- Determine the criteria and methods to ensure effective operation and control to achieve planned results and continual improvement.
- Ensure availability of information necessary for effective operation and monitoring of processes.
- Monitor, measure and analyse these processes.
- Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes must be managed in accordance with the Standard. Where an organisation chooses to **outsource** any processes that affect product conformity with requirements, the organisation **shall ensure control over such process**. Controls of such outsourced processes shall be identified within the Quality Management System.

Auditor Note

Examples of where this requirement could be seen to apply includes such things as:

- Receipt of items for inclusion into a finished product.
- Obtaining a crew from a Manning Agent.

It would be expected that where outsourcing has been used a fairly strict discipline of "Approval and Performance Evaluation" within purchasing controls would be implemented.

Documentation Requirements

The Standard does prescribe that the documentation must include:

A) Documented Statements of a Quality Policy and Quality Objectives.
B) A Quality Manual.
C) Documented Procedures required by this International Standard.
D) Documents needed by the organisation to ensure the effective planning, operation and control of its processes etc.
E) Quality records required by this International Standard.

Notes are added to specify that "Documented Procedure" means established, documented, implemented and maintained – and a further note also states that documentation can be in any form or type of media.

Auditor Note

In summary the Standard specifies inclusions for the Quality Manual and outlines the requirements for and intentions of, Document Control and within the overall Section 4.2 includes the control of Quality Records requirements.

However, the specified inclusions for the Quality Manual – Section 4.2.2. – do have one or two important considerations for Auditors:

1) The Scope of the QM including details of any justifications for any exclusion.
2) A description of the interaction between the processes in the QMS.

Both of these will have an impact on both the "Document Review" and the Site Audit, as an Auditor must verify the acceptability of these inclusions.

5.6

MANAGEMENT RESPONSIBILITY

This Clause has the following Sections and Sub-sections:

- **Management Commitment**
- **Customer Focus**
- **Quality Policy**
- **Planning:**
  Quality Objectives
  Quality Management System Planning
- **Responsibility, Authority and Communication:**
  Responsibility and Authority
  Management Representative
  Internal Communication
- **Management Review:**
  General
  Review Input
  Review Output

Management Commitment

Top Management shall provide **evidence** of its commitment to the development of the Quality Management System by:

A) Communicating the importance of meeting Customer and Legal and Regulatory requirements.
B) Establishing the Quality Policy and the Quality Objectives.
C) Performing Management Reviews.
D) Ensuring the availability of necessary resources.

Auditor Note

This requirement to provide "Evidence" can be fairly easily initially satisfied but this commitment MUST be continually reviewed in Surveillance and later Audits as the commitment should be demonstrated by "achievement" against Policy and Objective Statements and follow through of Management Review conclusions and recommendations. See later lecture on "Auditing Commitment".

Customer Focus

This Clause clearly embraces the first principle of Management in 9004. The Management must ensure that the Customer requirements are determined and fulfilled **with the aim of enhancing Customer satisfaction** – Note **"Enhancing"** not simply achieving or maintaining. However, this emphasises the need for Customer focus by recognising that understanding the Customer requirements is fundamental for the whole system.

Auditor Note

It would be expected that a Company is moving towards an **increased level** of Customer satisfaction and this means present levels must be clearly understood,

Quality Policy

The Standard requires that Top Management shall ensure that the Quality Policy:

A) Is appropriate for the purpose of the Organisation.

B) Includes commitment to meeting requirements and **continually improves the effectiveness of the Quality Management System.**

C) **Provides a framework for establishing and reviewing Quality Objectives.**

D) Is **communicated** and understood within the Organisation.

E) **Is reviewed for continuing suitability**.

Auditor Note

The requirement to continually improve is perhaps one of the most fundamentally important requirements. This requirement does mandate actions and methods being implemented.

The requirement clearly acknowledges the need for the Quality Management System to be a "living document" and one that is proactive in responding to the challenges of the business environment.

The Standard requires that the Quality Policy provide the framework for establishing the Quality Objectives.

5.8

Quality Objectives

The Standard requires that:

- The Organisation shall ensure that the Quality Objectives including those needed to meet requirements for product are established at relevant functions and levels within the Organisation. The Quality Objectives shall be **measurable** and consistent with the Quality Policy.

Auditor Note

This is a clear alignment with ISO 14001. Unlike ISO 14001, the new Standard does not require that specific Management Programmes be devised and implemented to facilitate achieving the Quality Objectives.

It is the Quality Planning that allows the achievement of objectives. Objectives are then used as one of the factors facilitating continual improvement.

ISO 14001 requires the setting of both objectives and specific targets whereas ISO 9001:2000 only specifies the need for objectives and not specific targets – **HOWEVER** – the Standard does state that objectives shall be measurable which implies (at least) that some form of quantification will have to be adopted more often than not.

Because this need for "targets" is not specified and Auditors will have to evaluate – on a case-by-case basis the appropriateness of the established Objectives on the basis of:

- The Company Policy Statements.
- The overall intention of the Objectives.
- The ability of the non-specified Objective to be understood by those personnel involved in the achievement.
- The ability of Senior Management to understand levels of achievement where the Objective is specifically linked to an improvement initiative.

"Can it be measured?" has to be an Auditor's consideration in Audit of Objectives.

5.9

Quality Management System Planning

This Clause is now a Directive concerning the Management System being planned in such a way as to satisfy the overall general requirement (4.1.) **and** to ensure that Quality Objectives are achieved.

It also emphasises "Document Control" attributes by requiring that the integrity of the Management System be maintained when changes are planned and implemented.

Responsibility, Authority and Communication

Responsibilities, Authorities and their Interrelation must be defined and communicated.

5.10

Management Representative

This Clause states:

Top Management shall appoint a Member of the Management who, irrespective of other responsibilities shall have responsibility and authority that includes:

A) Ensuring that processes of the Quality Management System are established, implemented and maintained.

B) Reporting to Top Management on the performance of the Quality Management System, including needs for improvement.

C) **Ensuring the promotion, awareness, of Customer requirements throughout the Organisation.**

The requirement in item (C) significantly enhances the role of the Management Representative, adding the requirements for ensuring recognition of the fundamental element of Customer Focus in that Organisation.

A Note refers to Management Representative's potentially additional role in liaising with other parties in the matters related to QMS.

Internal Communication

It is required that the Organisation must ensure that there will be internal communication regarding the effectiveness of the Quality Management System.

<u>Auditor Note</u>

Bearing in mind the overall focus on the Standard, an Auditor should spend a considerable length of time examining the way in which the Company addresses certain key communication issues:

- The "individuals" role in the achievement of Customer satisfaction.
- The "individuals" importance in the achievement of Continual Improvement Objectives and the requirements of these Objectives.

MANAGEMENT REVIEW

General

The Top Management must review the Quality System at planned intervals to ensure continued suitability, adequacy and effectiveness. The review must assess opportunities for improvement and the need for changes to the Quality Management System, including Policy and Objectives.

The requirement to review the need for change emphasises that the system must evolve with the Organisation. The "planned intervals" are unspecified, but the input information to be considered is defined along with required output of the Review Process.

Review Input

It is required that the Management Review should include review of current performance and improvement opportunities related to:

A) **Audit results.**
B) Customer feedback.
C) Process performance and product conformance.
D) Status of preventive, corrective actions.
E) Follow-up actions from earlier Reviews.
F) Planned changes that could affect the QMS.
G) Recommendations for improvement.

Again it is clear that the emphasis of the Review is/should be **PERFORMANCE** and **IMPROVEMENT**.

Review Output

The Output is also defined to include actions related to:

A) Improvement of the Quality Management System.
B) Improvement of product related to Customer requirements
C) Resources needs.

The Standard also requires that results of Management Review must be recorded.

Auditor Note

The intention is obviously to strengthen the process and the involvement of Top Management. It is clear that Auditors should devote considerable attention to the evaluation of the effectiveness of the Review Process and the commitment this Review Process should demonstrate.

RESOURCE MANAGEMENT

Provision of Resources

This states that the Organisation must determine and provide the resources needed to implement and maintain the QMS and continually improve its EFFECTIVENESS. It also requires that these resources shall be those necessary to enhance Customer satisfaction by meeting Customer requirements.

This is another all-embracing statement that emphasises existing stated and implied requirements.

Human Resources

This Clause has two (2) Sub-sub-clauses:

- **General**
- **Competence, Awareness and Training**

General

Personnel performing work affecting product quality shall be **competent** on the basis of appropriate education, training, skills and experience.

Using the word "Competent" emphasises the importance of ensuring that people are suitably qualified for what they do.

Competence, Awareness and Training

The Clause requires that the Organisation shall:

A) Identify **competency** needs for personnel performing work affecting product quality.

B) Provide training or take other action to satisfy these needs.

C) **Evaluate the effectiveness of actions taken**.

D) **Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives.**

E) Maintain appropriate records of education, training, skills and experience.

Auditor Note

Organisations are required to **evaluate the effectiveness of training**. Organisations will need to have in place a mechanism, which will allow them to evaluate the effectiveness of training.

Ensuring awareness of the relevance and importance of their activities is a requirement, which again clearly aligns the approach with ISO 14001. It is an important inclusion as lack of awareness of how important it is to achieve conformance with the requirements, often leads to problems – again this is a direct alignment with 14001 requirements.

Infrastructure

The Organisation is required to define, provide and maintain the infrastructure (facilities) needed to achieve the conformity of product.

The infrastructure can include:

- Buildings, workspace and associated facilities.
- Process equipment, both hardware and software.
- Supporting services such as transport or communication.

Work Environment

The Organisation shall determine and manage the work environment needed to achieve conformity to product requirements.

Auditor Note

The Standard provides a very short and general statement on the need to manage this aspect of the organisation's activities and an Auditor **must** be aware of which "environmental" aspects can and do affect quality and therefore require Formal Management within a QMS.

Health and Safety in the workplace should be "commented on" if not acceptable but not reported on unless such issues also lead to quality non-conformity.

PRODUCT REALISATION Requirement 7

This Clause covers the Product Realisation Processes required.

Planning of Product Realisation

This Clause explains that Product Realisation is a sequence of processes and sub-processes required to achieve the product. Planning of the realisation processes must be consistent with other requirements of the Quality Management System and must be documented in a manner that suits the Organisation's method of operation.

In planning the Organisation must determine as appropriate:

A) Quality Objectives for the Product, Project or Contract.

B) The need to establish processes and documentation and provide resources specific to the product.

C) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptability.

D) The records that are necessary to provide evidence that the realisation processes and resulting product fulfil requirements.

The output of this planning shall be in a form suitable for the organisation's method of operations.

A Note explains that a document specifying (all of the things mentioned) can be referred to as a Quality Plan. A further Note explains that the Organisation may also apply the requirements of Clause 7.3. to the development of product realisation processes – "Design and Develop a Process".

Auditor Note

This makes it a requirement for all Companies to provide an "output in a form suitable for the organisation's methods of operations" which means this is fully auditable.

The "Quality Plan" must be specific to the product so, if a Company has more than one (1) product there must be more than one (1) Quality Plan and the Quality Plan(s) produced would have to be evaluated for their completeness and accuracy.

5.15

CUSTOMER RELATED PROCESSES

This Clause has three (3) Sub-clauses:

- **Determination of Requirements Related to the Product.**
- **Review of Requirements Related to the Product.**
- **Customer Communication.**

Determination of Requirements Related to the Product

This Clause requires identification of Customer Requirements. It requires that the process must determine:

A) Requirements specified by the Customer, including requirements for the delivery and post delivery activities.

B) **Requirements not stated by the Customer but necessary for specified use or known and intended use**.

C) **Statutory and Regulatory requirements related to the product**.

D) Any additional requirements determined by the Organisation.

Review of Requirements Related to the Product

This Clause requires that the Customer requirements together with other determined requirements are reviewed before a commitment to supply is made to the Customer. The review must ensure that:

A) Product requirements are defined.

B) Contract or Order requirements differing from those previously expressed are resolved.

C) The Organisation has the ability to meet the defined requirements.

Where the Customer provides no documented statement of requirements these are confirmed prior to acceptance. Where product requirements are changed the Organisation shall ensure that relevant documents are amended and that personnel are made aware of the changed requirements. A note is added to state that in some situations, such as internal sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

5.16

Customer Communications

This Clause of the Standard requires that the Organisation implement arrangements for communication with Customers relating to:

A) Product information.

B) Enquiries, contract or order handling, including amendments.

C) Customer feedback, including Customer complaints.

<u>Auditor Note</u>

This Clause should present little real difficulty in auditing approaches. The only area where specific requirements have been "spelt-out" concerns:

- Requirements not stated by the Customer but necessary for specified, known or intended use and this should be linked with Statutory and Regulatory requirements of the product.

Clearly an Auditor should be examining ***"Are there implied or mandated needs and have they been recognised by the Company?"***

The addition of the Note in Clause 7.5.4. dealing with "Intellectual Property" will/may have particular relevance to the way in which an organisation manages situations where their customers provide information and/or details of proprietary design during "Contract Review" communications.

5.17

DESIGN AND DEVELOPMENT

This Clause has seven (7) Sub-clauses:

- **Design and Development Planning**
- **Design and Development Inputs**
- **Design and Development Outputs**
- **Design and Development Review**
- **Design and Development Verification**
- **Design and Development Validation**
- **Control of Design and Development Changes**

Auditor Note

Product – and indeed Service (as a product) – development can be seen to be applicable (for example) where an existing design is further enhanced by new or changed:

- Customer Requirements.
- Legislative or Regulatory Requirements.
- Enhanced reliability Requirements – driven by Management Improvement Criteria.

Design and Development Planning

The general Clause states that "The Organisation shall Plan and Control Design and Development of the Product". Design and Development Plans include:

A) Stages of the design and development process.

B) Review, verification and validation activities appropriate to each design and/or development stage.

C) Responsibilities and authorities for design and development activities.

Interfaces between different groups involved in design and development shall be managed to ensure effective communication and clarity of responsibilities.

Planning output shall be updated as appropriate, as the design and/or development progresses.

Design and Development Inputs

Inputs relating to Product requirements shall be defined and documented. These shall include:

A) Functional and performance requirements.

B) Applicable Regulatory and Legal requirements.

C) Requirements **derived from previous similar designs**.

D) Any other requirements essential for design and development.

These inputs shall be reviewed for adequacy and incomplete, ambiguous or conflicting requirements shall be resolved. It should be noted that there is a re-emphasis of Legal/Regulatory requirements.

Design and Development Outputs

The Design Output must be documented in the manner that allows verification against the input requirements and must:

A) Meet the input requirements.

B) Provide appropriate information for production and/or service operation.

C) Contain or reference acceptance criteria.

D) Specify characteristics that are essential for safe and proper use of product.

Design and Development Review

The purpose is clearly defined as follows:

A) Evaluate the ability to fulfil the requirements.

B) Identify problems and propose the development solutions.

Review must involve all those concerned with the design stage being reviewed and results of review including any follow-up actions must be recorded.

Design and Development Verification

This clause states, "Design and Development Verification shall be performed to ensure the output meets the design input requirements. The results of verification and subsequent follow-up actions shall be recorded".

Design and Development Validation

This Clause requires that Validation be performed in accordance with planned arrangements to assure that the resultant product or service(s) is capable of meeting the requirements for the intended use. The full validation wherever possible should be undertaken prior to delivery.

By using "wherever possible" the Standard clearly acknowledges that partial validation may be necessary/possible.

Control of Design and Development Changes

Design and Development changes shall be identified, documented and controlled. This includes evaluation of effect of the changes on component parts and delivered products and/or services. The changes shall be verified and validated, as appropriate and approved before implementation. The results of review of changes and subsequent follow-up actions must be documented.

Auditor Note

The inclusion of the requirements for the Organisation ***"To consider the effect of design and development changes can have on constituent parts"*** will NOT ONLY be that physical changes may have to be evaluated as being necessary or not BUT ALSO it is likely that the sections of a Company QMS dealing with this requirement will have to have very clear considerations of the need to revise "Product Realisation Process" planning when design and development change occurs.

PURCHASING

- **Purchasing Process**
- **Purchasing Information**
- **Verification of Purchased Product**

Purchasing Process

The organisation must control its purchasing process to ensure that purchased product conforms to specified purchasing requirements. The type and extent of control will depend on the impact of purchased product on the subsequent realisation processes and their output.

The supplier must be evaluated and selected based on their ability to supply product in accordance with the organisation's requirements. Criteria for selection evaluation and periodic re-evaluation must be defined. The result of evaluations and follow-up actions must be recorded.

Purchasing Information

The purchased product must be described including where appropriate:

A) Requirements for approval of product, procedures, processes, equipment.

B) Requirements for qualification of personnel.

C) Quality Management System requirements.

The Organisation must ensure adequacy of specified requirements prior to release of purchasing documents.

Verification of Purchased Product

The requirements for pre-shipment verification whether proposed by the organisation or by the customer have been combined into single simple sentence. If such verification is proposed the arrangements and method for product release must be specified in purchasing information.

PRODUCTION AND SERVICE PROVISION

The five (5) Sub-clauses include:

- **Control of Production and Service Provision**
- **Validation of Process for Production and Service Provision**
- **Identification and Traceability**
- **Customer Property**
- **Preservation of Product**

Control of Production and Service Provision

This Clause states: The Organisation shall plan and carry out production and service provisions under controlled conditions – including:

A) The availability of information that specifies the characteristics of the products.

B) The availability of Work instructions.

C) The use of suitable equipment.

D) The availability and use of measuring and monitoring devices.

E) The implementation of monitoring and measurement.

F) The implementation of release, delivery and post delivery activities.

Validation of Processes for Production and Service Provision

The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The established arrangements for these processes shall include, as applicable:

A) Defined criteria for review and approval of the processes.

B) Approval of equipment and qualification of personnel.

C) Use of specific methods and procedures.

D) Requirements for records.

E) Revalidation.

Identification and Traceability

The organisation shall identify, where appropriate, the product by suitable means throughout product realisation.

The organisation shall identify the status of product with respect to measurement and monitoring requirements.

Where traceability is a requirement the organisation shall control and record the unique identification of product. A note identifies that in some industry sectors, Configuration Management is a means by which identification and traceability are maintained.

Customer Property

The wording is clear in stating that the care of customer's property needs to be exercised whilst it is under the organisation's control or being used by the organisation.

It has added a Guidance Note that advises that customer property may include intellectual property e.g. information provided in confidence. The new requirement is really only the absolute definition of "Intellectual Property" although it should be noted that documented procedures are not explicitly required.

Auditor Note

This requirement, including "Intellectual Property" could be seen as a move to counter the worldwide trend in "Product Piracy". Auditors in this area should take care, as it is obviously legally and physically dangerous to enter into direct discussion on this topic. However, an auditor should examine such things as:

- Security of Customer information/design related to a manufactured product or service provided.
- Control/Balancing of materials specific and unique to a particular Clients "Copyrighted" product or service being manufactured under license to ensure "over-runs" are accounted for.
- Production of "Own Name Brands" that are similar/identical to "Trade Mark Brands" also under production.

5.24

Preservation of Product

"The Organisation shall preserve the conformity of the product with Customer requirements during internal processing and final delivery to intended destination.

"This shall include, where applicable, identification, handling, packaging, storage and protection."

"Preservation shall also apply to constituent parts of a product."

CONTROL OF MONITORING AND MEASURING DEVICES

Organisation must determine monitoring and measurements to be made and measurements and measuring devices needed to ensure conformance of product.

Processes shall be established to ensure that monitoring and measurements can be carried out and are carried out in a manner that is consistent with measurement requirements.

Where necessary, to ensure valid results, measuring equipment shall:

A) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to International or National Measurement Standards; where no such Standards exist, the basis used for calibration or verification shall be recorded.

B) Be adjusted or re-adjusted as necessary.

C) Be identified to enable the calibration status to be determined.

D) Be safeguarded from adjustments that would invalidate the measurement results.

E) Be protected from damage and deterioration during handling, maintenance and storage.

In addition the Organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation shall take appropriate action on the equipment and any product affected. Records of the results of calibration shall be maintained.

When used in monitoring and measurement the ability of computer software to satisfy the intended application shall be confirmed. This should be undertaken prior to initial use and reconfirmed as necessary.

MEASUREMENT, ANALYSIS AND IMPROVEMENT
Requirement 8

This Clause is Sub-divided as follows:

- **General**

- **Monitoring and Measurement:**
  Customer Satisfaction
  Internal Audit
  Monitoring and Measurement of Process
  Monitoring and Measurement of Product

- **Control of Non-conforming Product**

- **Analysis of Data**

- **Improvement:**
  Continual Improvement
  Corrective Action
  Preventative Action

GENERAL

The Organisation must plan and implement monitoring, measurement, analysis and improvement processes needed:

A) To demonstrate conformity of product.

B) To ensure conformity of the QMS.

C) To continually improve the effectiveness of the QMS.

This must include the determination of need for use of applicable methodologies including Statistical Techniques.

MONITORING AND MEASUREMENT

Customer Satisfaction

As one of the measurements of performance of the QMS the Organisation shall monitor information relating to Customer **perception** as to whether the Organisation has fulfilled Customer requirements. The methods for obtaining and using the information shall be determined.

9004 Guide to Improvement

Management and monitoring of Customer satisfaction is based on review of customer related information. The collection of such information may be active or passive. Management should recognise that there are many sources of customer related information and should establish effective and efficient processes to collect analyse and use this information for improving the performance of the organisation.

Examples of Customer related information include:

- Customer and user surveys.
- Feedback on aspects of product.
- Customer requirements and contact information.
- Market needs.
- Service delivery data.
- Information related to competition.

The Management of the organisation should plan and establish processes to listen to "The voice of the customer". Planning should define and implement data collection methods, including sources, frequency and data analysis review. Sources can include:

- Customer complaints.
- Communication direct with customer.
- Questionnaires and surveys.
- Sub-contracted collection and analysis of data.
- Focus groups.
- Reports from consumer organisation.
- Reports in media.
- Sector and industry studies.

Auditor Note

An Auditor should always consider the "appropriateness" of the Company's defined methods for addressing this requirement and whatever they are they should obviously go beyond simple "Customer Complaints".

It may be advisable before auditing this element of a Company's QMS for the Audit Team to have examined Clause 7.2. and if applicable to the Scope of Activity Clause 7.3.

This will ensure, at least, that an initial understanding of Customer requirements related to the process and product has been established in order for the Auditor to be able to initially understand conclusions on "Customer Satisfaction".

Internal Audit

The requirements are:

Conduct Audits at planned intervals to determine whether the QMS:

A) Conforms to the Planned Arrangements (7.1.), to the requirements of this International Standard and to the QMS requirements established by the Organisation.

B) Is effectively implemented and maintained.

An Audit Programme shall be planned taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous Audits. The Audit Criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process – auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits and for reporting audits and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification results.

Auditor Note

Essentially the Company scheduling should reflect the relative importance of the various parts of the overall process established by the Company in "Planning – Clauses 4 and 5.

Monitoring and Measurement of Process

This Clause states:

The Organisation shall apply suitable methods for monitoring and where applicable, measurement of the QMS processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken as appropriate to ensure conformity of the product.

Monitoring and Measurement of Product

The Organisation shall monitor and measure the characteristics of the product to verify that product requirements are fulfilled. This shall be carried out at appropriate stages of the product realisation process in accordance with Planned Arrangements (7.1.).

Evidence of conformity with the acceptance criteria shall be maintained.

Product release and service delivery shall not proceed until all the planned activities have been satisfactorily completed, unless otherwise approved by a relevant Authority and where applicable the Customer.

CONTROL OF NON-CONFORMING PRODUCT

The requirements are:

- Action must be taken to eliminate the detected non-conformity.
- By authorising its use, release or acceptance under concession by a relevant Authority and where applicable by the Customer.
- By taking action to preclude its original intended use or application.

Records will be maintained – including concessions (4.2.4)

When non-conforming product is corrected it shall be subject to re-verification.

When non-conforming product is detected after delivery or use has started the Organisation shall take action appropriate to the effects or potential effects of the non-conformity.

ANALYSIS OF DATA

The Organisation shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

A) Customer satisfaction.
B) Conformance to product requirements.
C) Characteristics and trends of processes and products including opportunities for preventive action.
D) Suppliers.

Auditor Note

This requirement should lead to more substantive auditing decisions as auditors should, to the greatest possible extent, use "Company Data" as the basis for deciding "effectiveness" of the QMS.

IMPROVEMENT

This Clause has three (3) Sub-clauses:

- **Continual Improvement**
- **Corrective Action**
- **Preventive Action**

Continual Improvement

The Organisation shall continually improve the effectiveness of the QMS through the use of the Quality Policy - Quality Objectives - Audit Results - Analysis of Data - corrective and Preventive Actions and Management Reviews.

Auditor Note

Whatever the decisions taken by senior management on the need for, and areas of, improvement the auditor should ensure that these decisions are logical and appropriate to the actual circumstances of the company's relationship with customers, regulators, and competitors etc.

Corrective Action

The important elements are:

A) Reviewing non-conformity including Customer complaints.

B) Determining the cause.

C) Evaluating the need for action to prevent recurrence.

D) Determining and implementing action needed.

E) Recording results of actions.

F) Reviewing corrective actions taken.

Preventive Action

The Organisation shall determine actions to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the **potential** problems.

A documented procedure shall:

A) Define requirements for determining potential non-conformities and their causes.

B) Define requirements for evaluating the need for action to prevent occurrence of non-conformities.

C) Define requirements for determining and implementing action needed.

D) Define requirements for records of results of action taken.

E) Define requirements for reviewing preventive action taken.

Auditor Note

In order for an Organisation to be able to demonstrate that they are capable of this preventative approach they must/should be able to demonstrate that they have "analysed" the process and identified "quality risks" – Failure Mode and Effect Analysis (FMEA) could be a useful discipline as one option here.

ISO 9001:2000		
Clause	Title	Content
1.0	Scope	
1.1	General	To meet customer and regulatory requirements
1.2	Application	Applicable to all organisations unless an area may be considered for exclusion
2.0	Normative References	Describing reference standards
3.0	Terms and Definitions	Spells out that “organisation” replaces “supplier”; also that “product” can mean, “service”.
4.0	Quality Management System	
4.1	General Requirements	The need to identify “processes” and their interaction. Also to have sufficient resources and to be responsible for any out-sourcing.
4.2	Documentation Requirements	Spells out requirements for a Policy, a Quality Manual, other documents required and necessary records. Documents to be controlled and also records.
5.0	Management Responsibility	
5.1	Management Commitment	Must demonstrate commitment by communication and ensuring quality objectives are met. Must be Management Review and adequate resources.
5.2	Customer Focus	Must have customer satisfaction.
5.3	Quality Policy	Must be appropriately communicated to all and kept under constant review.
5.4	Planning	Must be implemented and measurable within the Quality Policy.
5.5	Responsibility, Authority & Communications	Responsibilities to be defined. A management representative appointed. Internal communications to be implemented.
5.6	Management Review	Planned at intervals to ensure it is effective. Both review input and output with strong emphasis on customer requirements.
6.0	Resource Management	
6.1	Provision of Resources	Provide sufficient resources to implement the system and enhance customer satisfaction.
6.2	Human Resources	Personnel shall be competent. Training to be provided and records kept.
6.3	Infrastructure	The organisation shall provide suitable infrastructure.
6.4	Work Environment	To be maintained to meet product requirements.

7.0	Product Realisation	
7.1	Planning of Product Realisation	Processes to be planned and objectives set. Records to be maintained.
7.2	Customer related processes	Customer requirements to be identified and also any regulatory requirements. Contract orders to be implemented and organisation capable to meet requirements. Clear communications with customers.
7.3	Design and Development	All areas to be controlled and reviews carried out. There will be both inputs and outputs ensuring all rules and regulations are complied with, including past design criteria and the process should be constantly reviewed. All design and development shall be capable of verification and validation and all changes must be agreed and records maintained.
7.4	Purchasing	Must ensure all purchased products meet requirements and suppliers are assessed. All products to be specified and verified prior to acceptance.
7.5	Production and Service Provision	Suitable work instructions and the use of equipment and monitoring devices to be available. Validation of processes to be available and to be capable of identification and traceability. Customer property to be looked after. Product to be preserved.
7.6	Control of Monitoring & Measuring Devices	Where monitoring and measuring devices are used in the process, they shall be capable of accurate measurement. They must be calibrated as required and protected.
8.0	Measurement, Analysis & Improvement	
8.1	General	Where required, the process must be implemented to measure, analyse and improve the effectiveness of the system.
8.2	Monitoring & Measurement	Organisation must monitor to ensure the customer requirements are being met. Internal audits to be implemented to ensure the system is meeting the requirements and ensure corrective actions are being taken.
8.3	Control of Non-conforming Product	The organisation must implement procedures to deal with non-conforming product either by reflection, segregation or rework.
8.4	Analysis of data	Suitable to be collected to ensure the management system is effective and that customer satisfaction is evident.
8.5	Improvement	Continuous improvement of the Quality System to be implemented and corrective action effective to achieve this. Preventive action is essential.

PART 6

THE ISM CODE

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INTRODUCTION TO THE ISM CODE

SCOPE OF ISM

The International Safety Management Code is a Safety Management System based on the Requirements of the International Standard ISO 9001:1994 which was the model for Quality Assurance in Production, Installation and Servicing. The ISM Code, however, relates specifically to the Safe Operation of Ships and Pollution Prevention, crucially it establishes, through the designated person(s), a direct link between the ship and the company.

The design and implementation of a Safety Management System will be influenced by the varying needs of a Ship Owner/Manager, the types of vessel being operated, the trade engaged in and the nature of the crew.

The Requirements specified are aimed specifically at achieving the safe operation of ships and pollution prevention.

Conformance with the ISM Code will require the Company's conformity to all applicable current International and National Legislation.

The Application of the Code will lead to the issue of two new Certificates, namely:

1. **The Document of Compliance (DOC)** that will be issued to the Company following a successful Audit of the shore-side aspects of the Safety Management System:

    * Objective evidence will be required in order to demonstrate that the system has been in operation for a minimum of three months in addition to similar evidence of operation on a least one ship of each type in the fleet.

    * It will be specific to ship type(s) at the time of Audit.

    * It will be valid for five years, and

    * It will be subject to Annual Verification (+ or - three months of the anniversary date).

2. **The Safety Management Certificate** (SMC) that will be issued to individual ships after an onboard Audit of the SMS;

    * Objective evidence will be required to demonstrate that the SMS has been in operation on board the ship for a minimum of three months before the Audit.

    * The Company must be in possession of a valid DOC, a copy of which must be placed on board the ships.

* It will be valid for five years, and

* Will be subject to one intermediate verification between the second and third anniversaries, with the proviso for more frequent audits if deemed necessary by the Flag Authority.

The International Maritime Organisation's International Safety Management Code for The Safe Operation of Ships and Pollution Prevention is now mandatory under SOLAS '74 Chapter IX.

In order to differentiate between Quality and Safety, the following definitions are applicable:

Quality: Meeting a specified or implied need.

Safety: The control of accidental loss.

While Quality and Safety have different meanings, they are closely inter-related and both depend on the Quality of the Organisation. Safety Management Systems are 85% of a Quality Management Systems.

It is generally accepted that efficiency influences the financial performance of a Company, but the effects of Safety on profits are still greatly underestimated.

The definition of an accident can be stated as:

Everything that happens which was not planned - but costs money.

Therefore the Quality of Transportation (Shipping) Services -

i.e. *Getting the right cargo, to the right place, in the right condition, at the right time*

- Depends not only on the Quality of the Organisation, but also on the Operational Safety.

A QUALITY/SAFETY MANAGEMENT SYSTEM

The ISM Code aims to ensure the Safety of Life at Sea, prevention of human injury, loss of life and avoidance of damage to the environment and to property. The Code stipulates that Companies should develop, implement and maintain Safety Management Systems. Having said this, neither ISO 9000 series nor the ISM Code set out to dictate to Companies how to run their business, it is up to each Company to clearly document their Procedures in accordance with the Code and to effectively implement these Procedures.

Using the Discipline of Quality Assurance, Companies must "write what they do and provide objective evidence that they do what they have written".

A Safety Management System (which is easily incorporated into a Quality System) must include:

* A Safety & Environment Protection Policy.
* Procedures and Instructions to ensure the Safe Management and Operation of Ships and Pollution Prevention.
* Conformance with relevant International and National Rules and Regulations.
* Defined levels of authority and clear lines of communication between and amongst the Management ashore and the Management onboard each vessel.
* Procedures for reporting accidents, non-conformances and hazardous occurrences.
* The control and issue of all documentation (procedures and instructions).
* Procedures for preparing for and responding to emergency situations.
* Procedures for the maintenance of the ships.
* Procedures for Internal Audits ashore and onboard and Management Reviews of the developed and implemented systems to ensure they are effective.
* Companies must appoint a Designated Person to be responsible for the Management system, providing the vital link between Management ashore and Management onboard ship. **The Designated Person must have direct access to the highest level of Management ashore.**

Auditing for the ISM Certification will be carried out by Flag Administrations, many of whom have already embarked upon achieving ISO 9001:2000 Quality Assurance Certification themselves, whilst some Flag States may appoint Recognised Organisations to conduct the Audits on their behalf (Resolution 739(A) 18).

Audits will be carried out throughout the Management ashore and onboard ships to verify effective implementation of Safety Management Systems throughout the entire Company.

Once a Company Audit has been satisfactorily completed:

* *A Document of Compliance* will be issued for the shore side aspects of the Safety Management System, and

* *A Safety Management Certificate* will be issued to individual ships after an onboard Audit of the S.M.S.

The implementation of the Code will ensure the endorsement of the Master’s ultimate responsibility in a clear statement from the Company.

Shore and Shipboard Manuals, which define job responsibilities of employees, must define the Master's role, covering implementation of the Company's Objectives, Policies, crew motivation and necessity of issuing clear, brief Orders and Instructions. The documented system should ensure that Verification and Review of the Company's Systems would enable all deficiencies to be reported and systems altered or improved if necessary before mishaps occur.

The commitment to successfully implementing Quality, including Safety, Management Systems must come from Senior Management and must involve all personnel both ashore and onboard the ships.

THE ELEMENTS OF THE ISM CODE

1. Definitions.
2. Safety and Environmental Policy.
3. Company Responsibilities and Authority.
4. Designated Person(s).
5. Master's Responsibility and Authority.
6. Resources and Personnel.
7. Development of Plans for Shipboard Operations
8. Emergency Preparedness.
9. Reports and Analysis of Non-Conformances, Accidents and Hazardous Occurrences.
10. Maintenance of Ship and Equipment.
11. Documentation.
12. Company Verification, Review and Evaluation.
13. Certification and Periodical Verification.
14. Interim Certification
15. Verification
16. Forms of Certificates

THE ISM CODE

ISM 1: Definitions

Audit/Assessment: A systematic and independent examination to determine if activities and related results comply with Planned Arrangements and whether these arrangements are implemented effectively and are suitable to achieve the stated objectives.

Objective Evidence: Information, which can be proved true, based on facts obtained through observation, measurement, test or other means.

Non-conformance: Non-fulfilment of a specified requirement.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Safety: State in which the risk of harm (to persons) or damage is limited to an acceptable level.

ISM 2: The Safety Management System and Policy

The Safety Management System encompasses all the required documentation associated with the maintenance of safety of crew, ship, property and environment. The system may be complete in its own right or assembled from a number of Manuals, Reference Books and Publications and Company Edicts. In the vast majority of cases it will comprise the latter in which case a Register of Reference Material should be maintained to show that all such publications are kept up to date.

Policy: The Company's Policy Statement on Safety and Pollution Prevention.

The Company must clearly and concisely set out its objectives relative to the safe operation of their vessels and pollution prevention. This message must be conveyed to **all** personnel who may have an effect on achieving this objective and will include those employed ashore, afloat and Sub-contracted to the Company. Commitment and authorisation must be from the highest level. In support of the Company Policy there will be other Policy Statements addressing Drug and Alcohol abuse, Health and Safety and any other important areas that require addressing.

Having satisfactorily stated in the Policy Statement what the Company does, the Safety Management System must adequately describe how the Policy goals are achieved by describing the relevant authorised Procedures that in turn should be supported by the necessary Work Instructions and Guidance Notes.

Evidence of the System being implemented, communicated and understood by **all** relevant personnel should be available by means of each person recording their dated signature.

ISM 3, 4, 5 and 6: Company Responsibility and Authority

It will be necessary to determine initially from the formalised Procedures and Instructions that the Company has developed the required standards throughout the Organisation and that they are being implemented and followed by all relevant personnel. This will be reflected in the allocation of resources - human, material and financial to ensure that all International and National Rules and Regulations are realised and stated objectives in the Policy Statement can be achieved.

The Company Organogram should clearly identify all "key personnel" which must include the **Designated Person(s)** ashore. This person's ability to report to the C.E.O. if required must be clearly defined.

The authorities and responsibilities of these key personnel should be identified in their job descriptions and Management personnel ashore as well as ship's Officers/Ratings require to be properly identified. The **responsibility & authority of the Master** must be clearly defined.

The Company's commitment to providing adequately qualified, experienced and medically fit Officers and Ratings must be shown in Procedures and supported by Records.

Procedures showing commitment to training of personnel both ashore and afloat must be adequate for the activities and tasks they are required to perform. Procedures must cover Induction Training for new and temporary appointments and subsequent training following reported Performance Appraisals.

ISM 7: Shipboard Operations

Communication, cargo operations, stability, navigation, safety, environment protection, and security must all be addressed by adequate written Procedures and Work Instructions and verified by ample records.

It will be evident that crews are adequately trained to carry out the tasks allotted to them and there is in place sufficient Reference Material to assist them where this is necessary or access to personnel ashore who can advise.

The Procedures and especially the Company's Instructions must address all the points necessary to ensure that the ships are operated in a safe manner with sufficient consideration given to the trade being engaged in.

To ensure adequate control of the Safety Management System, it is necessary that **Identification and Traceability** of material, equipment and services can be accomplished. This will involve effective Procedures for reporting, monitoring, communicating and maintaining proper records.

ISM 8: Emergency Preparedness

The Company must have in place adequate Procedures to quickly and effectively deal with all identifiable incidents. These Procedures must enumerate the types of emergency and the frequency of exercise to be conducted by the ship's crew.

A minimum List of Drills is given in the **"Guidelines on the Application of the ISM Code".**

The Procedures must cover the requirement that all such drills and training be analysed and recorded along with any accidents which occur. The feedback received by Management ashore from accidents, incidents, safety committee meetings, near misses and emergency drills must be followed up and fully logged.

The Company will also show in the Procedures how Shore Management will assist and support the Master during emergency incidents.

Records should show what analysis has been carried out following accidents and exercises, the corrective action taken and evidence of the effectiveness of the actions.

ISM 9: Reports and Analyses of Non-Conformities, Accidents and Hazardous Occurrences

The Procedures must include provision for ensuring that non-conformities, accidents and hazardous occurrences/situations are reported promptly to the Company, properly investigated and analysed with the aim of improving safety and avoiding pollution, whenever and wherever possible. The objective should be to prevent rather than cure the problems through the analysis of recorded occurrences - be proactive, not reactive to the situations.

Corrective and preventive action will be monitored to ensure that the actions taken have proved effective.

ISM 10: Maintenance of the Ship and Equipment

The Procedures and Work Instructions must show how effective preventive maintenance of vessel structure and equipment is conducted and recorded; how inspections and reporting is handled and how repairs are managed. The method of reporting condition and defects from the ships and the follow up ashore must be recorded and adequate to maintain an acceptable standard of operational efficiency. The frequency of inspections will be partly determined by Classification requirements and partly by Company and Manufacturer's requirements. Records of replacement and renewal will be kept.

A Procedure for controlling and overseeing dry-dock repairs must be in place including procedures for testing and commissioning of repaired plant.

ISM 11: Control of Documentation and Data

In order that the system can operate effectively and be kept up to date with everyone following the same International, National and Company requirements, all Manuals must be properly controlled, as must the distribution of the Manuals. These must be available to all relevant personnel. Approval of Policies, Procedures and Work Instructions must be identified. Amendments to the documentation throughout the Company must be effectively controlled.

ISM 12: Auditing

The Company must have a proper Procedure and records to show that adequate auditing has been carried out both ashore and on board to ensure that their Safety Management System remains effective. The Procedure must allow for new or amended legislation, new operating techniques and technology, as well as Customer requirements.

The importance and complexity of activities and the findings of previous audits will govern the frequency of Safety Audits.

Safety awareness can be established by asking questions of all relevant personnel. The "guide" or other Manager or Head of Department in attendance during the Assessment should not be allowed to answer on behalf of the person to whom questions are directed and this must be made clear at the Opening Meeting.

The records must show what non-conformances have been found during Internal Audits and what action to correct these non-conformances has been authorised and carried out. The corrective action must show that the corrective actions have been effective and remain effective.

Audits must be supported by properly minuted Management Review Meetings, which clearly show that all related safety, and pollution matters are discussed at the highest level and effective corrective action taken where necessary.

Objective of the Audit: To verify that an Owner/Manager's Safety Management System meets and continues to meet specified requirements and is being effectively implemented.

It should be shown that the Company’s Safety Management System:

* Provides for safe practices in ship operation and a safe working environment.

* Establishes safeguards against all identified risks, and

* Continuously improves Safety Management Skills of personnel ashore and onboard ship with special emphasis on preparation for emergencies and environmental protection.

ISM 13, 14, 15 & 16: Certification

The ship should be operated by a Company which has been issued with a Document of Compliance or with an Interim Document of Compliance relevant to that ship.

The Document of Compliance is only valid for the ship types explicitly indicated in the document.

The Safety Management Certificate should be issued to a ship for a period not exceeding five years. The validity of the certificate should be subject to at least one intermediate audit.

COMMUNICATIONS/REPORTING RECORDING

The cornerstone of any Safety Management System is communication. It is essential that this requirement be considered in great depth when developing the SMS to ensure that all personnel are aware of their responsibilities, authorities, inter-relationships and skills required to safely perform their tasks and functions. It is necessary for the Company to ensure that all personnel are fully aware of what the Company expects of them and to provide the necessary instruction and support to all personnel. The Company must be kept advised of the day-to-day status of the ships, crew, cargo and progress of the voyage, which will require adequate reporting, and feedback from the ships, with acknowledgement and advice from ashore.

If the foregoing is conducted properly the Company will function as an effective and efficient unit. This will, however, require the creation and implementation of suitable Policies, Procedures and Work Instructions with adequate attention to review to ensure consistency.

Analysis and review of accidents, hazardous occurrences, non-conformances and recommendations for improvement along with effective corrective action will ensure that the SMS is capable of producing the required results and remain effective.

Adequate records require to be maintained in order to ensure that sufficient identification, traceability, distribution of information and instruction is achieved and that necessary objective evidence is available for meaningful Audits and Assessments to be conducted.

EFFECTIVE RECRUITMENT/TRAINING

The explicit responsibilities of Shipping Companies in the revised STCW Convention are as follows:

Responsibilities of Companies

Each Administration (i.e. Flag State) shall hold Companies responsible for the assignment of seafarers for service in their ships in accordance with the provisions of the STCW (1978) Revised 1995 Convention, and shall require every such Company to ensure that:

Appropriate Certificates

1. Each seafarer assigned to any of its ships holds an appropriate Certificate in accordance with the provisions of the Convention and as established by the Administration.

The revised Convention also states that seafarers on board will have to be able, if required, to present originals of their Certificates for inspection. In other words, photocopies will not be sufficient.

The *'Appropriate Certificates'* that Companies will have to ensure seafarers hold will include:

* The National Certificate of Competence.
* An Endorsement from the Government issuing the National Certificate attesting that it meets STCW Standards (this may be incorporated into the National Certificate).
* Individual Flag State Endorsements - contained in separate documents-which Flag States are required to issue to seafarers whose Certificates, have been issued by another Government. A three months' grace period is allowed between the date when a seafarer joins a Foreign Flag ship and the date of Endorsement issued by the Flag State, provided that documentary proof that an application for an Endorsement has been made can be presented.

In order to help Companies ensure that seafarers hold appropriate Certificates the revised Convention contains the following new provisions:

* Companies will be entitled to request Foreign Administrations to confirm that Certificates issued to seafarers serving on their ships are actually valid and authentic.
* Governments will be required to maintain a Register of all Certificates and Endorsements for Masters and Officers which are issued or revalidated and those which have been suspended, cancelled, reported lost or destroyed.

The ability of Companies to comply with requirements concerning seafarers' Certificates will thus in part be clearly dependent on Governments also fulfilling their new responsibilities.

Manning

2. Its ships are manned in conformance with the applicable Safe Manning Requirements of the Administration.

Manning in conformance with applicable Flag State Requirements includes conformance with the Safe Manning Document or equivalent, which the SOLAS Convention requires Flag States to ensure are carried on board their ships. *IMO Resolution A. 481 (IX)* (on Principles of Safe Manning) recommends that the Safe Manning Document should specify the number and qualifications of personnel required to be carried on a ship from a safety standpoint.

Evidence of conformance will involve a check that seafarers hold the appropriate Certificates as described above.

Record Keeping

3. Documentation and data relevant to all seafarers employed on its ships are maintained and readily accessible, and include, without being limited to, documentation and data on their experience, training, medical fitness and competency in assigned duties.

Companies will have to ensure that documentation regarding seafarers' experience, training, medical fitness and competence in assigned duties is readily accessible. However, this task could be delegated to Manning Agents or other Third Parties.

The *ISF Manning Agents Policy* contains guidance on the maintenance of full and complete records, relevant to Shipping Companies or Manning Agents and the type of records that should be kept.

Shipboard Familiarisation

4. Seafarers on being assigned to any of its ships are familiarised with their specific duties and with all ship arrangements, installations, equipment procedures and ship characteristics that are relevant to their routine or emergency duties.

The Company shall provide written instructions to the Master of each ship to which the Convention applies, setting forth the Policies and Procedures to be followed to ensure that all seafarers who are newly employed on board the ship are given a reasonable opportunity to become familiar with the shipboard equipment, operating procedures and other arrangements needed for the proper performance of their duties, before being assigned to those duties.

Allocation of a reasonable period of time during which each newly employed seafarer will have an opportunity to become acquainted with:

The specific equipment the seafarer will be using or operating, and

Ship specific WATCHKEEPING, safety, environmental protection and emergency procedures and arrangements the seafarer needs to know to perform the assigned duties properly, and

Designation of a knowledgeable crewmember who will be responsible for ensuring that an opportunity is provided to each newly employed seafarer to receive essential information in a language the seafarer understands.

Because these requirements relate to the specific equipment and procedures that seafarers need to be familiar with in order to perform their assigned duties on board, the extent to which Companies will have to apply them to personnel not directly involved with the operation of the ship may be limited. However, other new provisions contain further requirements concerning basic familiarisation in safety matters for all shipboard personnel and there are additional shipboard familiarisation requirements for certain personnel on Ro-Ro passenger ships.

Part B of the STCW Code contains further recommendatory guidance concerning shipboard familiarisation, which some Government's may decide to apply on a mandatory basis.

The *ICS/ISF Guidelines on the Application of the IMO International Safety Management Code* also contains advice on shipboard familiarisation procedures.

<u>Crew Co-ordination</u>

5. The ship's complement can effectively co-ordinate their activities in an emergency situation and in performing functions vital to safety or to the prevention or mitigation of pollution.

The requirement concerning the crew's ability to co-ordinate activities embraces the ability of crewmembers to communicate effectively with each other. It is possible that this aspect will have to be demonstrated to Port State Control Inspectors who may request that emergency drills are carried out if they have reason to believe that the crew may not in fact be capable of co-ordinating effectively.

In order for Shipping Companies to ensure that the ship's complement can effectively co-ordinate activities in an emergency situation; they will need to demonstrate the actions to counter emergency situations.

IMPLICIT NEW COMPANY OBLIGATIONS

Although not directly addressed to Shipping Companies, there are other major amendments to the STCW Convention that Companies must nevertheless be aware of in order to ensure that they comply with the Rules.

Additional Familiarisation, Basic Safety Training and Instructions

Further to the requirement that Companies must ensure that newly employed personnel are familiarised with equipment and procedures specific to their shipboard duties, Governments will also have to ensure that seafarers, on all ship types, undergo additional familiarisation and basic training in shipboard safety matters.

These regulations will apply to different categories of personnel as follows:

* **Familiarisation** in very elementary safety matters applying to all shipboard personnel other than passengers.

* **Basic Training** in more comprehensive safety matters applying, to seafarers with designated safety or pollution prevention duties in the operation of the ship, i.e. excluding most personnel who are not qualified officers or ratings.

Familiarisation in Safety Matters

Before being assigned to shipboard duties all persons employed on board or engaged on a seagoing ship other than passengers, shall receive approved familiarisation training in personal survival techniques or receive sufficient information and instruction. (In order to be able to know what to do in an emergency, accordance with STCW requirements explained below.)

This means that **all** personnel who are assigned to any shipboard duty will have to undergo familiarisation concerning elementary safety matters before being assigned their duties:

* **On cargo ships** this will include, for example, riding gangs, stewards and cooks.

* **On passenger ships** this requirement will apply to such personnel as waiters, bar staff, keep fit instructors, entertainers, shopkeepers and cleaners employed on board.

The process used to familiarise crew will have to be approved by the Flag State. However, the fact that this familiarisation in elementary safety matters can be provided by means of *sufficient information and instructions* implies that all personnel will not be required to attend a special training course and that the familiarisation can take place immediately after they arrive on board the ship. The familiarisation could comprise verbal instruction, written materials and videos.

The familiarisation required will have to be sufficient to ensure that all personnel are able to:

1. Communicate with other persons on board on elementary safety matters and understand safety information symbols, signs and alarm signals.

2. Know what to do if:

   A person falls overboard.
   Fire or smoke is detected, or
   the fire or abandon ship alarm is sounded.

3. Identify muster and embarkation stations and emergency escape routes.

4. Locate and don life jackets.

5. Raise the alarm and have basic knowledge of the use of portable fire extinguishers.

6. Take immediate action upon encountering an accident or other medical emergency before seeking further medical assistance on board.

7. Close and open the fire, weathertight and watertight doors fitted on the particular ship other than those for hull openings.

Basic Safety Training or Instructions

More comprehensive training or instruction in safety and emergency matters has to be undertaken by *seafarers with designated safety* or pollution prevention duties. Principally such persons will only include officers and ratings and such members of the Catering Department as are designated to carry out these duties.

The required training or instruction includes:
* Personal survival techniques.
* Fire prevention and fire fighting.
* Elementary first aid, and
* Matters such as emergency procedures, pollution prevention and occupational safety.

The STCW Code specifies detailed standards of competence relating to these areas. In practice, most seafarers should already be receiving the required training, either at College or during seagoing service, as part of their existing training courses prior to qualification.

Governments are permitted to exempt certain seafarers from some of these basic training requirements, but only if they consider them to be impractical on account of ship size or voyage pattern.

SPECIAL TRAINING FOR PERSONNEL ON CERTAIN TYPES OF SHIP

Ro-Ro Passenger Ships

In addition to the familiarisation and basic training mentioned above, the revised Convention requires that personnel serving on Ro-Ro passenger ships, including many personnel not directly connected with operation of the ship, have to undergo extra, ship specific training.

The scope of this additional training varies considerably according to the category of personnel.

The method of training undertaken by personnel on Ro-Ro passenger ships has to be approved by the Flag State. However, personnel are not required to attend additional training courses and any training that does not form part of existing shore based training courses can be conducted on board the ship. In most countries, the Company is responsible for issuing documentary evidence to personnel stating that training has been completed and that they are appropriately qualified.

Other Passenger Ships

The special requirements for Ro-Ro passenger ships were adopted as a direct response to the *Estonia* tragedy. However, the Conference requested IMO, as a matter of urgency, to develop - where relevant - similar additional training requirements for personnel on other types of passenger ships.

The Conference also recommended Flag State to extend the relevant training requirements for Ro-Ro passenger vessels to other passenger ships on a National basis before these additional amendments are developed. Many Flag States have done this.

Tankers

The training requirements for personnel on tankers remains essentially unchanged in substance from the current Convention, although extensive recommendatory guidance on the structure of training courses is included in Part B of the STCW Code.

GMDSS REQUIREMENTS

Every person in charge of or performing radio duties on a ship operating under the Global Maritime Distress and Safety System (GMDSS) requires an appropriate GMDSS Certificate as required by the ITU Radio Regulations. However, under a separate provision this requirement also applies to Officers in Charge of a Navigational Watch.

In practice, this means that most, but not all, Governments require Candidates in navigation to obtain a General Operator's Certificate (GOC). Shipping Companies therefore need to ensure that the qualifications of any foreign seafarers that they employ match the certification requirements of the Flag State.

ENGLISH LANGUAGE REQUIREMENTS

The revised Convention includes several references to expanded English language requirements for seafarers.

* Officers of the navigational watch require knowledge of written and spoken English adequate to understand charts, nautical publications, meteorological information and messages concerning the ship's safety and operation and adequate to communicate with other ships and coast stations and multilingual crew and use IMO Standard Maritime Communication Phrases.

* Officers of the navigational watch required to comply with standards of competence for GMDSS Radio Operators and obtain GOC Certificates require knowledge of English, both written and spoken, for the communication of information relevant to the safety of life at sea.

* Engine watchkeepers are required to demonstrate ability adequate to interpret engineering publications written in English and to speak clearly and comprehensibly when making communications needed to perform engineering duties.

* Recommendatory guidance in Part B of the STCW Code concerning basic training for seafarers with designated safety or pollution prevention duties suggests that Flag State should consider ensuring that seafarers have an ability to use at least an elementary English vocabulary with an emphasis on nautical terms and situations.

KNOWLEDGE OF MARITIME LAW

Flag States are required to ensure that Officers serving on their ships at the Management level (i.e. Senior Officers) holding Certificates issued by another Government have an appropriate knowledge of the Flag State's Maritime Legislation, relevant to the functions they are permitted to perform.

PREVENTION OF DRUG AND ALCOHOL ABUSE

Amongst the watchkeeping requirements in the revised Convention, which have been consolidated into a single chapter, is recommendatory guidance relating to the prevention of drug and alcohol abuse. The extent to which Governments implement this advice will in part depend on the degree to which it conflicts with existing National Legislation relating to issues such as the rights of individuals.

Governments are advised to prescribe a maximum of 0. 08% blood alcohol level (BAC) for seafarers during watchkeeping, and to prohibit alcohol consumption within 4 hours prior to serving as a member of the watch. Governments are also recommended to establish *screening programmes* which will identify drug and alcohol abuse.

NEW CERTIFICATION REQUIREMENTS

Survival Craft

The Certificate of Proficiency in Survival Craft (CPSC) is extended in scope and now covers rescue boats, other than fast rescue boats.

Fast Rescue Boats

A new standard of competence applies to personnel required to launch and take charge of fast rescue boats in emergency situations and the relevant personnel have to be certificated.

Advanced Fire Fighting

Detailed standards of competence and evaluation apply to personnel designated to control fire-fighting operations. If this training is not included in the qualifications for the designated seafarer's STCW Certificate a special certificate or documentary evidence is required.

Medical Care

New standards of competence - broadly based on existing ILO Requirements - apply to seafarers designated to provide first aid on board at a level higher than that required as part of basic training requirements and to seafarers designated to take charge of medical care on board. Special certificates or documentary evidence that an appropriate training course has been completed are required if not covered by the seafarer's STCW Certificate.

EXPLICIT NEW COMPANY RESPONSIBILITIES

The explicit responsibilities of Shipping Companies in the revised Convention are as follows:

Responsibilities of Companies

Each Administration (i.e. Flag State) shall hold Companies responsible for the assignment of seafarers for service in their ships in accordance with the provisions of the present (1995) Convention and shall require every such Company to ensure that:

Appropriate Certificates

1. Each seafarer assigned to any of its ships holds an appropriate Certificate in accordance with the provisions of the Convention and as established by the Administration.

Manning

2. Its ships are manned in conformance with the applicable Safe Manning Requirements of the Administration.

Record Keeping

3. Documentation and data relevant to all seafarers employed on its ships are maintained and readily accessible, and include, without being limited to, documentation and data on their experience, training, medical fitness and competency in assigned duties.

Shipboard Familiarisation

4. Seafarers on being assigned to any of its ships are familiarised with their specific duties and with all ship arrangements, installations, equipment procedures and ship characteristics that are relevant to their routine or emergency duties, and

Crew Co-ordination

5. The Ship's complement can effectively co-ordinate their activities in an emergency situation and in performing functions vital to safety or to the prevention or mitigation of pollution.

RISK ANALYSIS/ASSESSMENT

1. Whilst the Shipping Industry has been "informally" managing the safety of its operations for many years, the ISM Code is a formalised attempt to apply a structured approach to operational and environmental safety.

2. A Safety Management System is a control mechanism working to defined parameters (Policies, Procedures, Rules and Regulations etc.); which through inspection, investigation and Audit, monitors and evaluates the process, identifies errors, and effects suitable corrective action. It is an ongoing, pro-active activity, designed to be constantly updating and improving the Systems and developing a comprehensive "Safety Culture".

3. Risk Assessment is defined as the evaluation of the likelihood of an undesired event (hazard), and of the resulting harm or damage caused.

   The principal stages of any risk assessment are :

   * Identifying the potential hazard.
   * Analysing how this may occur.
   * Considering the extent of its effect(s).
   * Considering the likelihood of its occurrence.
   * Making judgements about the significance of the identified hazard.
   * Incorporating actions that will reduce the likelihood or consequence of the hazard. (Risk Management).

4. Whilst the ISM Code states: (1.2.2.) that a Company should "establish safeguards against all identifiable risks", and (10.3) "establish Procedures in the SMS to identify equipment and technical systems the sudden operational failure of which may result in hazardous situations", it does not impose any detailed requirements upon the Company. For compliance, the Company itself must address those risks inherent in its own specific operations.

5. Risk Assessment of a Safety Management System requires four key activities:

   * Development
   * Implementation
   * Monitoring
   * Review

RISK ASSESSMENT

DEVELOP CONTROLS

IMPLEMENT CONTROLS **Feedback**

MONITOR THE SYSTEM

REVIEW THE SYSTEM

A. DEVELOPMENT

Development of measures of control would include:

* The design process.
* Documentation (Safety and Environmental Protection Policy; Procedures, Safety Management Manual; Safety Plans; Emergency Contingency Plans and the incorporation of relevant National and International Rules and Regulations).
* Recruitment, selection and training of personnel.
* The provision of adequate resources.

B. IMPLEMENTATION

Once the Company has developed controls, it must be assured that they will be fully complied with, so implementation of these controls can be achieved through:

* Management demonstrating commitment to safety and promoting the "safety culture".
* Ensuring all Employees (ship and shore) are aware of their responsibilities to safety through training, job descriptions, procedures, and relevant and accessible Company Manuals.
* The promotion of safety through a variety of communication channels.
* Implementing regular Audits and Inspections.

C. MONITORING ACTIVITIES

These are pro-active activities that determine the compliance (or not) of those control measures that have been developed and implemented by the Company.

* **Audit**
  This is a major exercise - organised by:

  - The Designated Person - internally - as per the Audit Schedule of the Office and all the ships (See Chapter on Audit).
  - A Third Party as per the Contractual arrangements, but for the DOC this will occur annually, and for the SMC(s), every thirty (30) months.

* **Survey**
  A detailed review of one section of the SMS.

* **Inspection**
  A formal assessment of workplace safety.

D. REACTIVE SAFETY MONITORING.

An activity which occurs in the event of an accident or incident (near miss), or when an unsafe condition has been identified - (often a failure of the SMS). The intention of this activity is:

* To establish facts prior to, during and after the event - including:

  - Personnel involved.
  - Time and date.
  - Weather conditions.
  - Sequence of events.
  - Extent of damage, injury etc.

* To determine:

  - Were existing SMS controls adequate ?
  - Were existing SMS controls being complied with ?

* To identify training needs, deficiencies in the SMS control mechanism.

* To provide records/statistics of the event for future reference and to be able to detect trends.

E. REVIEW

Regular review of the SMS provides the necessary feedback mechanism to ensure that the Company is continuously improving the SMS and ensuring that it covers all the potentially hazardous activities in which the Company is involved. It also ensures that all relevant corrective action has been implemented and that it is effective.

Emergency Response and Contingency Planning

Under Requirement 8 of the ISM Code, a Company should establish Procedures to identify, describe and respond to potential emergency shipboard situations. The Company should also establish programmes for drills and exercises. The Company's System must be able to respond at any time to hazards, accidents or emergency situations, which involves Company ships.

The aspects of contingency planning, both shore based and shipboard, as depicted in the ICS Guidelines, is very much a proactive, forward thinking measure, indicating that the Company, having identified potential emergency shipboard operations, will develop programmes, drills and exercises to be able to account for them.

The programme of drills should be additional to those required by the SOLAS Convention, and conducted to develop and maintain confidence and proficiency onboard. However, the requirement to address emergency is Company wide, and extends back to Head or Local Office and thus the plans, as appropriate, should mobilise the Shore Based Management, Emergency Contingency Plans under simulated conditions.

Ideally, the Company should have an assigned Emergency Response Team from Staff in the Office, headed by a Senior Manager who has overall control and has the authority to make decisions on behalf of the Company. The specially selected Team ensures that as much expertise can be utilised as quickly as possible, to assist the Master of a ship on a wide variety of requirements in a time of stress. The Team will thus perhaps comprise:

* The Designated Person(s).
* A Fleet Manager.
* An Engineering Superintendent.
* A person who has expert knowledge of the cargoes being carried, and the likely reaction of mixing, contamination, spills etc.
* A person who works with Charter Parties, Cargo Claims, Insurance etc.
* A person in contact with various Regulatory Bodies - MSA, P&I etc.

A Directory should be developed containing all telephone contact numbers (Office, home, mobile etc.) of all relevant personnel, and relevant Bodies and Institutions, a copy of which should be retained by all of the above and all the Company vessels. It is vital that this Directory is maintained up-to-date.

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The Directory should also detail the procedure to be followed in the event of an emergency. The Master onboard is responsible for ensuring all Senior Officers onboard are familiar with the System.

One of the key contingency planning functions is to ensure adequate communications are constantly available. The Emergency Team should have their own dedicated, direct phone lines.

The Senior Manager/Managing Director should be trained to be able to deal proficiently with the Media - to ensure good corporate image is maintained.

Contingency Plans must be regularly practised, and made as realistic as possible. After drills or exercises, the results should be analysed to ensure the plan is effective, and any deficiencies highlighted should be immediately corrected and checked for improvement.

RISK MANAGEMENT

Definitions

Risk Assessment	"An evaluation of the likelihood of undesired events (Hazards) and the harm or damage caused"
Risk	"The chance or probability of exposure to hazard, combined with the consequences of such exposure" Probability of hard occurring i.e. Hazard severity *x* likelihood of occurrence.
Hazard	"Potential for harm"
Safety	"The state in which the risk of harm to a person or damage is limited to an acceptable level" *Acceptable Level* - As Low As Reasonably Practicable (ALARP)
Risk Analysis	"Identification of hazards and hazardous situations and determining the level of risk associated with each"
Risk Evaluation	"To determine the need for preventive and corrective action to control the level of risk"
Accident	"An undesired event that results in harm to people, damage to property or loss to process"
Incident	"An undesired event, which under slightly different circumstances could have resulted in harm to people, damage to property or loss to process"
Safety Culture	"The Safety Culture of an Organisation is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to and the style and proficiency of an Organisation's Health and Safety Management"

THE ELEMENTS OF THE ISM CODE

1. Definitions
2. Safety and Environmental Policy
3. Company Responsibilities and Authority
4. Designated Person(s)
5. Master’s Responsibility and Authority
6. Resources and Personnel
7. Development of Plans for Shipboard Operations
8. Emergency Preparedness
9. Reports and Analysis of Non-Conformities, Accidents and Hazardous Occurrences
10. Maintenance of the Ship and Equipment
11. Documentation
12. Company Verification, Review and Evaluation
13. Certification, Verification and Control
14. Interim Certification
15. Verification
16. Forms of Certificates

SAFETY AND ENVIRONMENTAL POLICY

- Prevention of human injury or loss of life.

- Avoidance of damage to the environment, in particular to the marine environment.

- Avoidance of damage to property.

- Management Commitment.

- Corrective Action.

- ALL to be involved in potential hazard identification.

Example of a S&E Policy

A. SHIPPING COMPANY
SAFETY AND ENVIRONMENTAL POLICY - ISM CODE REQUIREMENTS

The Company has identified safety and environment as two key areas in its sphere of operations that are of paramount importance and need to be effectively controlled to prevent unnecessary injuries, loss of life, damage to health, property and degradation of the environment.

To meet this requirement the Company has embraced the IMO's International Safety Management Code within its Quality System. The Quality including Safety Management System is designed to ensure the Company's activities are sufficiently controlled to protect personnel, property and the environment from all risks and hazards that can be reasonably expected.

The Company also recognises that an effective Quality, Safety and Environmental Protection Programme makes for a more profitable operation and thereby ensures the welfare of all involved in the business both ashore and at sea.

Safety is the concern of all and has no rank. However, to be effective it has to be management led. To this end, the Management is committed to making all personnel more safety conscious and encourage all to become actively involved in identifying possible hazards, implementing Corrective Action and constantly monitoring all facets of their working environment to ensure Quality/Safety conditions prevail.

An accident is indicative of a failure in the operating system and the Company is committed to fully investigating all accidents or near miss incidents. The results of such investigations and any necessary Corrective Action will be brought to the attention of all concerned so as they may learn from the incident.

Learning is a never-ending journey to the road of excellence and effective training is fundamental to the Company's business and its safety culture. As our standards improve, new goals and targets will be set to which all personnel shall strive to attain.

Signed: _____ Date: _____

RESPONSIBILITIES AND AUTHORITY

- RESPONSIBILITIES (TO AND FOR)
- AUTHORITY
- REQUIRED LEVEL (S) OF COMPETENCE
- RELEVANT QUALIFICATIONS AND EXPERIENCE

DESIGNATED PERSON (S)

RESPONSIBILITIES

- Suitably qualified and experienced in the safety and pollution control aspects of ship operations (i.e. a Master or Chief Engineer).

- Fully conversant with the Company's Safety and Environmental Policy.

- Have the independence and authority to report deficiencies to the highest level of Management.

- Responsible for Safety Audits.

- Ensure Corrective Action has been taken.

MASTER'S RESPONSIBILITY AND AUTHORITY

5.1. The Company should clearly define and document the Master's responsibility with regard to:

1. Implementing the Safety and Environmental Protection Policy of the Company.

2. Motivating the crew in the observation of that Policy.

3. Issuing appropriate orders and instructions in a clear and simple manner.

4. Verifying that specified requirements are observed;

   and

5. Reviewing the SMS and formally reporting its deficiencies to the shore based Management.

RESOURCES AND PERSONNEL

6. 1. The Company should ensure that the Master is:

1. Properly qualified for command.

2. Fully conversant with the Company’s SMS.

3. Given the necessary support so that the Master's duties can be safely performed.

6.2. The Company should ensure that each ship is manned with qualified, certificated and medically fit seafarers in accordance with **N**ational and International Requirements.

6.3. The Company should establish procedures to ensure that new personnel and personnel transferred to new assignments related to safety and protection of the environment are given proper familiarisation with their duties. Instructions, which are essential to be provided prior to sailing, should be identified, documented and given.

6.4. The Company should ensure that all personnel involved in the Company's SMS have an adequate understanding of relevant rules, regulations, codes and guidelines.

6.5. The Company should establish and maintain procedures for identifying any training that maybe required in support of the SMS and ensure that such training is provided for all personnel concerned.

6.6. The Company should establish procedures by which the ship’s personnel receive relevant information on the SMS in a working language or languages understood by them.

6.7. The Company should ensure that the ship's personnel are able to communicate effectively in the execution of their duties related to the SMS.

SOME METHODS OF FAMILIARISATION

Send information on the Company's SMS and ship detail to the seafarer prior to joining the ship, requiring return documentation from the seafarer, which acknowledges receipt and indicates an understanding of its content.

Provide induction familiarisation on the ship, its equipment and the SMS upon joining, under the direction of the appropriate Officer.

Require the seafarer to complete a Questionnaire or Guided Programme, which entails self-familiarisation of the ship, its equipment, and the SMS. Ensure that the completed programme is handed to the Master or appropriate Senior Officer within a reasonable period of joining.

Allow a period of 'hand over' between seafarers joining and leaving the ship and make use of developed Checklists.

Develop a Video Familiarisation Package(s) for use on board or ashore conveying the concept of the SMS and its specific requirements. The video package might be used in conjunction with physical familiarisation on ship specific procedures or other requirements.

RELEVANT RULES

DEALING WITH THE SHIP

- SOLAS 1974
  (International Convention for the Safety of Life at Sea).

- MARPOL 73/78.
  (International Convention for the Prevention of Pollution from Ships 1973).

- COLREGS
  (Convention on the International Regulations for Preventing Collisions at Sea, 1972).

- International Convention on Load Lines 1966.

DEALING WITH THE SHIPOWNER

- IMO Resolution A.441 (XI).

DEALING WITH THE SEAFARER AND THE SHIP

- ILO Convention 147
  (Merchant Shipping (Minimum Standards) Convention 1976).

DEALING WITH THE SEAFARER

- STCW 1978
  (Convention on Standards of Training, Certification and Watchkeeping for Seafarers 1978). (Revised 1995).

- IMO Resolution A.481 (XII)
  (Principles of Safe Manning).

- IMO Resolution A.443 (XI).

SPECIAL SHIPBOARD OPERATIONS

EXAMPLES:

* Ensuring watertight integrity.

* Navigational safety, including the correction of charts and publications.

* Operations affecting the reliability of equipment (such as steering gear) and associated standby machinery.

* Maintenance operations.

* Bunkering operations and oil transfers in port.

* Maintaining stability and preventing overloading and overstressing.

* Lashing of containers, cargo and other items.

* Ship security, terrorism and piracy.

CRITICAL SHIPBOARD OPERATIONS

EXAMPLES:

* Navigation in confined waters or high-density traffic areas.

* Operations that may cause a sudden loss of manoeuvrability in close or high-density traffic waters.

* Navigation in conditions of reduced visibility.

* Operations in heavy weather conditions.

* The handling and stowage of hazardous cargoes and noxious substances.

* Bunkering and oil transfer at sea.

* Cargo operations on gas, chemical and oil tankers.

* Critical machinery operations.

SUBJECT MATTER FOR OPERATIONS

DOCUMENTATION

1. GENERAL

2. THE SHIP IN PORT

3. PREPARING FOR SEA

4. THE SHIP AT SEA

5. PREPARING FOR ARRIVAL IN PORT

SHORE BASED CONTINGENCY PLANS

POSSIBLE INCLUSIONS

* Composition and duties of persons acting within Contingency Plan.

* Procedures for mobilisation of an appropriate Company Emergency Response (Team).

* Procedures to follow in response to different types of accidents/hazards.

* Procedures for establishing and maintaining contact between ship and shore Management (Refer to IMO Resolution A648-16).

* Availability of ship particulars, plans, stability information, and safety and environmental protection equipment carried on board.

* Checklists appropriate to type of emergency to assist systematic questioning of ship during response.

* Lists of contact names and telecommunication details of all relevant parties.

* Reporting methods for both ship and shore Management (see IMO Resolution A648-16).

* Procedures for notifying and liasing with next of kin of persons onboard.

* Procedures for issuing information bulletins to and answering queries from the media and public.

* Back up arrangements for the Company's initial response in the event of a protracted emergency.

* The rostering of Company personnel and specialists dedicated to support the response and adequate relief for the maintenance of their routine duties.

SHIPBOARD CONTINGENCY PLANS

POSSIBLE INCLUSIONS

* Allocation of duties and responsibilities on board.
* Actions to be taken to regain control of a situation.
* Communication methods to be used on board.
* Procedures for requesting assistance from Third Parties.
* Procedures for notifying the Company and reporting to relevant Authorities.
* Maintaining communications between the ship and the shore.
* Procedures for dealing with the media or other outside parties.

Contingency Plans should be established to describe how to deal with emergency situations related to Damage, Fire, Pollution, Personnel, Security and Cargo.

EXAMPLES OF EMERGENCY SITUATIONS

* Structural failure.
* Main engine failure.
* Steering gear failure.
* Electrical power failure.
* Collision.
* Grounding/Stranding.
* Shifting of cargo.
* Cargo spillages or contamination.
* Fire.
* Cargo jettisoning.
* Flooding.
* Machinery room casualty.
* Abandoning ship.
* Man overboard/search and rescue.
* Entry into enclosed spaces.
* Serious injury.
* Terrorism or Piracy.
* Helicopter operations.
* Heavy weather damage.

PUBLICATIONS TO ASSIST SHIPBOARD OPERATION AND EMERGENCY PLANS

CARGOES

Code of Safe Practice for Cargo Stowage and Securing.

Code of Safe Practice for Ships Carrying Timber Deck Cargoes.

Code of Safe Practice for Solid Bulk Cargoes (BC Code).

International Maritime Dangerous Goods Code (IMDG Code) and Supplement.

Medical First Aid Guide for Use in Accidents Involving Dangerous Goods (MFAG).

MARINE ENVIRONMENT PROTECTION

Guidelines for the Development of Shipboard Oil Pollution Emergency Plans.

Manual on Chemical Pollution.

Provisions Concerning the Reporting of Incidents Involving Harmful Substances Under MARPOL 73/78.

NAVIGATION

Merchant Ship Search and Rescue Manual (MERSAR Manual).

Ship's Routeing.

INDUSTRY

Model Shipboard Oil Pollution Emergency Plan (as required by MARPOL 73/78, Annex 1, Regulation 26).

Pirates and Armed Robbers, A Masters' Guide.

(Both available directly from the Intentional Chamber of Shipping).

INDUSTRY PUBLICATIONS

Bridge Procedures Guide (ICS).

Contingency Planning and Crew Response Guide for Gas Carrier Damage at Sea and in Port Approaches.

Guide to Contingency Planning for the Gas Carrier Alongside and Within Port Limits (ICS/OCIMF/SIGTTO).

Guide to Contingency Planning for Marine Terminals Handling Liquefied Gases in Bulk (ICS/OCIMF/SIGTTO).

Guide to Helicopter/Ship Operations (ICS).

International Safety Guide for Oil Tankers and Terminals (ISGOTT) (ICS/OCIMF/IAPH).

Liquefied Gas Handling Principles on Ships in Terminals (SIGTTO).

Peril at Sea and Salvage - A Guide for Masters (ICS/OCIMF).

Prevention of Oil Spillages Through Cargo Pumproom Sea Valves (ICS/OCIMF).

Safety in Chemical Tankers.
Safety in Liquefied Gas Tankers.
Safety in Oil Tankers (ICS).

Ship-to-Ship Transfer Guide (Liquefied Gases) (ICS/OCIMF).

Ship-to-Ship Transfer Guide (Petroleum) (ICS/OCIMF).

Tanker Safety Guide (Chemicals) (ICS).

Tanker Safety Guide (Liquefied) (ICS).

REPORTS AND ANALYSIS OF NON-CONFORMITIES, ACCIDENTS AND HAZARDOUS OCCURRENCES

9.1. The SMS should include procedures ensuring that non-conformities, accidents and hazardous situations are reported to the Company, investigated and analysed with the objective of improving safety and pollution prevention.

9.2. The Company should establish procedures for the implementation of corrective action.

MAINTENANCE OF THE SHIP AND EQUIPMENT

10.1 The Company should establish procedures to ensure that the ship is maintained in conformity with the provisions of the relevant Rules and Regulations and with any additional requirements that may be established by the Company.

10.2 In meeting these requirements the Company should ensure that:

1. Inspections are held at appropriate intervals.
2. Any non-conformity is reported with its possible cause, if know.
3. Appropriate corrective action is taken; and
4. records of these activities are maintained.

10.3 The Company should establish procedures in the SMS to identify equipment and technical systems the sudden operational failure of which may result in hazardous situations. The SMS should provide for specific measures aimed to promoting the reliability of such equipment or systems. These measures should include the regular testing of stand-by arrangements and equipment or technical systems that are not in continuous use.

10.4 The inspections mentioned in 10.2 as well as the measures referred to 10.3 should be integrated in the ship's operational maintenance routine.

PREVENTIVE MAINTENANCE PROCEDURES FOR AT LEAST THE FOLLOWING

* Hull and superstructure steel work.
* Safety, fire-fighting and anti-pollution equipment.
* Navigational equipment.
* Steering gear.
* Anchoring and mooring equipment.
* Main engine and auxiliary machinery.
* Pipelines and valves.
* Cargo loading/discharging equipment.
* Inerting systems.
* Fire gas and heat detection systems.
* Bilge and ballast pumping and separator systems.
* Waste disposal and sewage systems.
* Communications equipment.

DOCUMENTATION

11.1 The Company should establish and maintain procedures to control all documents and data that are relevant to the SMS.

11.2 The Company should ensure that:

1. Valid documents are available at all relevant locations.

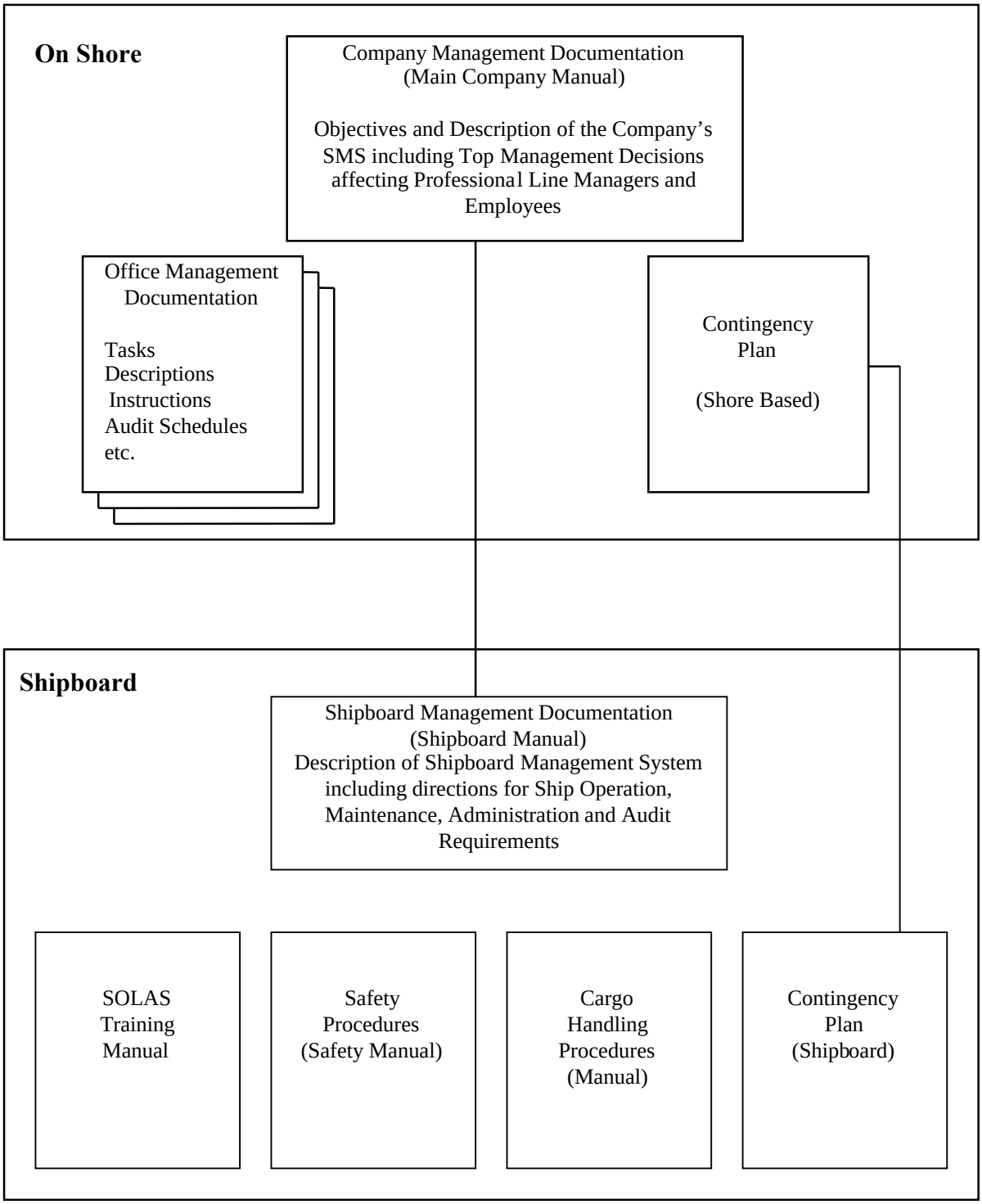
2. Changes to documents are reviewed and approved by authorised personnel, and

3. obsolete documents are promptly removed.

11.3 The document used to describe and implement the SMS may be referred to as the "Safety Management Manual".

Documentation should be kept in a form that the Company considers most effective. Each ship should carry on board all documentation relevant to that ship.

Possible structure for SMS documentation



COMPANY VERIFICATION REVIEW AND EVALUATION

12.1 The Company should carry out Internal Safety Audits to verify whether safety and pollution prevention activities comply with the SMS.

12.2 The Company should periodically evaluate the efficiency and when needed review the SMS in accordance with procedures established by the Company.

12.3 The Audits and possible corrective actions should be carried out in accordance with documented procedures.

12.4 Personnel carrying out Audits should be independent of the areas being audited unless this is impracticable due to the size and the nature of the Company.

12.5 The results of the Audits and reviews should be brought to the attention of all personnel having responsibility in the area involved.

12.6 The Management personnel responsible for the area involved should take timely corrective action on deficiencies found.

AUDIT REVIEW

* Organisational Management Structures.

* Administrative Procedures.

* Personnel, including their responsibilities and authority.

* Familiarity with the adherence to the SMS Policies, Procedures and Instructions.

* Requirements for additional familiarisation or ‘on the job’ ‘training’.

* Documentation reports and record keeping.

* Training and Certification.

MANAGEMENT REVIEW

* Analyses of accidents, hazardous occurrences and non-conformities.

* Audit findings.

* Recommendations following Class and Statutory Surveys.

* Considerations for updating the system as a result of fleet changes, trade and market strategies, new Regulations or changes in social and environmental attitudes.

CERTIFICATION AND PERIODICAL VERIFICATION

13.1 The ship should be operated by a Company, which has been issued with a Document of Compliance or with an Interim Document of Compliance in accordance with paragraph 14.1, relevant to that ship.

13.2 The Document of Compliance should be issued by the Administration, by an organization recognized by the Administration or, at the request of the Administration, by another Contracting Government to the Convention to any Company complying with the requirements of this Code for a period specified by the Administration which should not exceed five years. Such a document should be accepted as evidence that the Company is capable of complying with the requirements of this Code.

13.3 The Document of Compliance is only valid for the ship types explicitly indicated in the document. Such indication should be based on the types of ships on which the initial verification was based. Other ship types should only be added after verification of the Company's capability to comply with the requirements of this Code applicable to such ship types. In this context, ship types are those referred to in regulation IX/1 of the Convention.

13.4 The validity of a Document of Compliance should be subject to annual verification by the Administration or by an organization recognized by the Administration or, at the request of the Administration, by another Contracting Government within three months before or after the anniversary date.

13.5 The Document of Compliance should be withdrawn by the Administration or, at its request, by the Contracting Government which issued the Document when the annual verification required in paragraph 13.4 is not requested or if there is evidence of major non-conformities with this Code.

13.5.1 All associated Safety Management Certificates and/or Interim Safety Management Certificates should also be withdrawn if the Document of Compliance is withdrawn.

13.6 A copy of the Document of Compliance should be placed on board in order that the master of the ship, if so requested, may produce it for verification by the Administration or by an organization recognized by the Administration or for the purposes of the control referred to in regulation *IX/6.2 of the Convention. The copy of the Document is not required to be* authenticated or certified.

13.7 The Safety Management Certificate should be issued to a ship for a period which should not exceed five years by the Administration or an organization recognized by the Administration or, at the request of the Administration, by another Contracting Government. The Safety Management Certificate should be issued after verifying that the Company and its shipboard management operate in accordance with the approved safety management system. Such a Certificate should be accepted as evidence that the ship is complying with the requirements of this Code.

13.8 The validity of the Safety Management Certificate should be subject to at least one intermediate verification by the Administration or an organization recognized by the Administration or, at the request of the Administration, by another Contracting Government. If only one intermediate verification is to be carried out and the period of validity of the Safety Management Certificate is five years, it should take place between the second and third anniversary dates of the Safety Management Certificate.

13.9 *In addition to the requirements of paragraph 13.5.1, the Safety* Management Certificate should be withdrawn by the Administration or, at the request of the Administration, by the Contracting Government which *has issued it when the intermediate verification required in paragraph 13.8* is not requested or if there is evidence of major non-conformity with this Code.

13.10 Notwithstanding the requirements of paragraphs 13.2 and 13.7, when the renewal verification is completed within three months before the expiry date of the existing Document of Compliance or Safety Management Certificate, the new Document of Compliance or the new Safety Management Certificate should be valid from the date of completion of the renewal verification for a period not exceeding five years from the date of expiry of the existing Document of Compliance or Safety Management Certificate.

13.11 When the renewal verification is completed more than three months before the expiry date of the existing Document of Compliance or Safety Management Certificate, the new Document of Compliance or the new Safety Management Certificate should be valid from the date of completion of the renewal verification for a period not exceeding five years from the date of completion of the renewal verification.

INTERIM CERTIFICATION

14.1 An Interim Document of Compliance may be issued to facilitate initial implementation of this Code when:

.1 a Company is newly established; or

.2 new ship types are to be added to an existing Document of Compliance,

following verification that the Company has a safety management system that meets the objectives of paragraph 1.2.3 of this Code, provided the Company demonstrates plans to implement a safety management system meeting the full requirements of this Code within the period of validity of the Interim Document of Compliance. Such an Interim Document of Compliance should be issued for a period not exceeding 12 months by the Administration or by an organization recognized by the Administration or, at the request of the Administration, by another Contracting Government. A copy of the Interim Document of Compliance should be placed on board in order that the master of the ship, if so requested, may produce it for verification by the Administration or by an organization recognized by the Administration or for the purposes of the control referred to in regulation IX/6.2 of the Convention. The copy of the Document is not required to be authenticated or certified.

14.2 An Interim Safety Management Certificate may be issued:

.1 to new ships on delivery;

.2 when a Company takes on responsibility for the operation of a ship which is new to the Company; or

.3 when a ship changes flag.

Such an Interim Safety Management Certificate should be issued for a period not exceeding 6 months by the Administration or an organization recognized by the Administration or, at the request of the Administration, by another Contracting Government.

14.3 An Administration or, at the request of the Administration, another Contracting Government may, in special cases, extend the validity of an Interim Safety Management Certificate for a further period which should not exceed 6 months from the date of expiry.

14.4 An Interim Safety Management Certificate may be issued following verification that:

.1 the Document of Compliance, or the Interim Document of Compliance, is relevant to the ship concerned;

.2 the safety management system provided by the company for the ship concerned, includes key elements of this Code and has been assessed during the audit for issuance of the Document of Compliance or demonstrated for issuance of the Interim Document of Compliance;

.3 the Company has planned the audit of the ship within three months;

.4 the master and officers are familiar with the safety management system and the planned arrangements for its implementation;

.5 instructions, which have been identified as being essential, are provided prior to sailing; and

.6 relevant information on the safety management system has been given in a working language or languages understood by the ship's personnel.

VERIFICATION

15.1 All verifications required by the provisions of this Code should be carried out in accordance with procedures acceptable to the Administration, taking into account the guidelines developed by the Organization.*

FORMS OF CERTIFICATES

16.1 The Document of Compliance, the Safety Management Certificate, the Interim Document of Compliance and the Interim Safety Management Certificate should be drawn up in a form corresponding to the models given in the appendix to this Code. If the language used is neither English nor French, the text should include a translation into one of these languages.

16.2 In addition to the requirements of paragraph 13.3, the ship types indicated on the Document of Compliance and the Interim Document of Compliance may be endorsed to reflect any limitations in the operations of the ships described in the safety management system.

PART 7

GUIDELINES ON THE

INTERPRETATION OF THE

ISM CODE

Introduction	**7.1**
Scope and Field of Application	**7.1**
References	**7.2**
Quality/Safety System Requirements	**7.3**
Proposed Documented Quality/Safety System	**7.31**

GUIDELINES ON THE INTERPRETATION OF THE ISM CODE

INTRODUCTION

The Principles of good Management Systems have been generally agreed upon as reflected in the International acceptance of ISO 9000 Series of Quality Management and Quality Assurance Standards. These Principles may be successfully employed in a wide variety of Management Systems. As such, many of the Principles reflected in the Management System requirements of the ISO 9000 Series of Standards are employed by the **INTERNATIONAL SAFETY MANAGEMENT (ISM) CODE FOR THE SAFE OPERATION OF SHIPS AND FOR POLLUTION PREVENTION.**

ISO 9001:2000 focuses Management System elements on ensuring that Customer requirements for Quality are met. The ISM Code focuses on about 85% of the Management System elements employed by the ISO 9001:2000 for ensuring the Safe Management and Operation of Ships and Pollution Prevention.

SCOPE AND FIELD OF APPLICATION

The ISO 9001:2000 is written in language that may be applied to all Manufacturing and Service Industries, however it does not provide the Marine Industry with specific guidance on safety.

The International Management Code for the Safe Operation of Ships and for Pollution Prevention, known as the ISM Code, is a Safety Management System designed with the objective of ensuring safety at sea, prevention of human injury or loss of life, and avoidance of damage to the environment, in particular to the marine environment, and to property. [ISM 1.2.1].

These Guidelines are intended to be used as an aid to the interpretation of the requirements of ISO 9001:2000 as applied to *Marine Management and Ship Operations*. These Guidelines also frame the requirements of the *ISM Code* within the context of the ISO 9001:2000 elements.

These two “Standards”, though focusing on separate objectives, are in part complimentary in nature and may be implemented concurrently as one System. Alternatively, a properly designed Management System, compliant with the *ISM Code*, may be used as the foundation for subsequent development of a Management System fulfilling the requirements of both the *ISM Code* and ISO 9001:2000.

Companies implementing ISO 9001:2000 Systems compliant with the requirements of the ISM Code should be guided by the entire Section 7 Guidance Notes.

Companies seeking Certification under ISO 9001:2000 and/or *the ISM Code* should consider the impact of each element of these Standards upon quality of service, safety and pollution prevention in the operation of ships. The Organisation should apply only the applicable elements of these Standards to the services it provides.

The Marine Industry is subject to a range of requirements, many of which are implicit in Contracts involving Marine Operation. The Management System should ensure conformance with mandatory International and National Rules and Regulations and ensure that applicable Codes, Guidelines and Standards recommended by the IMO, Flag State Authorities, Classification Societies and Maritime Organisations are complied with.

Section numbers and titles are from ISO 9001:2000

REFERENCES

* ISO 9000:2000 Quality Management Systems – Fundamentals and Vocabulary.

* *ISM Code: International Safety Management Code for the Safe Operation of Ships and for Pollution Prevention, as contained in SOLAS 1974 Chapter IX.(amended July 2002)*

* ISO 9001:2000 Quality Management Systems – Requirements.

* ISO 9004:2000 Quality Management Systems – Guidelines for Performance Improvements.

* *SOLAS 74: International Convention for the Safety of Life at Sea.*

* *MARPOL 73/78: International Convention for the Prevention of Pollution from Ships.*

* *COLREGS (1972): Convention on International Regulations for Preventing Collision at Sea.*

* *STCW 78 (Revised 1995): International Convention on Standards of Training, Certification and Watchkeeping of Seafarers.*

* *ILO Conventions 147: Convention Concerning Minimum Standards in Merchant Ships (1976).*
* *ILO Convention 180: Seafarer's Hours of Work and the Manning of Ships (1996)*

* *ISGOTT: International Safety Guidelines for Oil Tankers and Terminals.*

* *OCIMF - Guidelines: Oil Companies International Marine Forum.*

* *ICS - International Chamber of Shipping: Applicable International Chamber of Shipping Guides.*

* *IMO - International Maritime Organisation Resolutions: International Convention on Load Lines (1966).*

Resolutions, Codes and requirements dealing with safety and environmental protection issued by IMO or other National, International or Industry recognised Organisations.

QUALITY/SAFETY SYSTEM REQUIREMENTS

(The requirements are numbered in accordance with IS0 9001:2000 together with the ISM numbering system where applicable).

ISO9001:2000 can be applied to safety, equally as well as quality, but Companies concerned solely with the ISM Code conformance should reference the portions in *Italics.*

4 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

The Organisation shall establish and maintain a documented Quality/Safety System as a means of ensuring that contractual requirements are fulfilled. The outline structure of the Quality System shall be defined in a Quality Manual. The Quality/Safety Manual shall provide reference to other pertinent Manuals and documented Procedures that form the Quality System.

The Organisation shall establish and maintain a documented Safety Management System (SMS) as a means of ensuring safe ship operation and pollution prevention. The SMS may be contained in a specific Manual which shall provide reference to other pertinent Manuals and documented Procedures that form the SMS. The SMS [ISM 1.2.2] *should:*

* *Provide for safe practices in ship operation and a safe working environment.*

* *Establish safeguards against all identified risks.*

* *Continuously improve safety skills of personnel ashore and onboard ships, including preparing for emergencies related both to safety and environmental protection.*

The Safety Management System shall ensure: [ISM 1.2.3]

* *Conformance with mandatory Rules and Regulations.*

* *That applicable Codes, Guidelines and Standards recommended by the Organisation, Administration, Classification Societies and Maritime Industry Organisations are taken into account.*

Each ship shall carry onboard all documentation relevant to that ship. Documentation shall be kept in a form understood by all Organisation personnel. [ISM 11.3]

The Management System shall be designed to support the stated Policies and accomplish associated objectives. The stated Policies include, but may not be limited to, the Quality Policy, Safety and Pollution Prevention Policy and Drug and Alcohol Policy (see 5.1*).*

Management System Structure

As was previously stated in Part 4 of these notes, a documented Management System typically consists of four levels of documentation:

Level 1

Level one consists of a Management System Policy Manual. The Organisation shall develop and maintain a Management System Manual. The Management System Manual shall:

* *Define the outline structure of the Management System.*

* *Contain the Management System Policies and associated objectives.*

* *Define the Scope and Field of Application of the Management System.*

* *Describe the Management System organisation and provide descriptions of the responsibility and authority of key Management personnel within the Organisation .*

* C*ross-reference elements of the Management System Manual to the applicable element of selected standard(s).*

Level 2

Level two consists of Management System Procedures describing the various activities of the functional areas included in the Quality and Safety Management System.

Level 3

Level three consists of:

* *Documented task or job specific instructions that augment employee skill to ensure control of the process.*

Level 4

* *Forms.*

* *Organisation Circulars/Edicts.*

A typical documented Quality/Safety System is identified in Figure 6A.

4.2 Documentation Requirements

4.2.1a Quality Policy

Responsibility for the commitment to Quality *(Safety)* rests with the highest level of Management. Organisation Management, with Executive responsibility for Quality *(Safety)*, shall define and document a clear and concise Quality *(Safety)* Policy that realistically reflects:

* Management's commitment to Quality *(Safety)*.
* Organisation objectives with regard to service Quality *(Safety)*.
* The standard of service provided.
* The method by which Quality *(Safety)* objectives will be achieved.

Customer requirements and expectations shall be considered when developing a Quality *(Safety)* Policy.

Safety and Environmental Protection Policy [ISM 2.1, 1.2.1]

Responsibility for and commitment to safety and pollution prevention rests with the highest level of Management. Organisation Management, with Executive responsibility for safety and pollution prevention, shall define and document a clear and concise Safety and Pollution Prevention Policy. The Safety and Pollution Prevention Policy shall describe how the following objectives will be achieved:

* *Prevention of human injury or loss of life.*

* *Avoidance of damage to the environment, in particular to the marine environment.*

* *Avoidance of damage to property.*

The Safety and Environmental Protection Policy shall be reviewed and amended as necessary to address relevant changes in Legislation, external and internal developments and occurrences to ensure that it remains effective.

Drug and Alcohol Policies

In the interest of promoting a healthy working environment, the Organisation will consider establishing and maintaining a Drug and Alcohol Policy, and appropriate procedures to control the use of drugs and alcohol. Procedures shall include suitable screening of personnel at the time of their employment as well as other methods necessary to maintain a substance free work place.

The Organisation shall ensure that applicable Quality, Safety and Pollution Prevention, and Drug and Alcohol Policies are developed, implemented and maintained at all levels of the Organisation both ashore and afloat. Copies of these Policies shall be available to all Organisation personnel. [ISM 2.2]

4.2.2 Quality (Safety) Manual

The organisation shall establish and maintain a quality (Safety) manual that includes

a) *The scope of the quality (Safety) management system,* including details of, and justification for any exclusions.
b) The documented procedures established for the Quality (Safety) Management System, or reference to them.
c) A description of the interaction between the processes of the Quality *(Safety)* Management System.

4.2.3 ***Control of Documents***

Documents required by the Quality (Safety) Management System shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4

A documented procedure shall be established to define the controls needed

a) To approve documents for adequacy prior to use
b) To review and update as necessary and re-approve documents
c) To ensure that changes and the current revision status of documents are identified
d) To ensure that relevant versions of applicable documents are available at points of use
e) To ensure that documents remain legible and readily identifiable
f) To ensure that documents of external origin are identified and their distribution controlled

Documents of external origin may include, but are not limited to:

* *Navigation Charts.*
* *Navigation Publications.*
* *National and International Regulations.*
* *Classification Rules.*
* *Manufacturers Technical Manuals.*
* *Time Charterer's Instructions.*
* *Ship's Drawings.*
* *Standard Charter Parties.*

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Note: *Documents and data can be in the form of hard copy, electronic, or other media.*

4.2.4 *Control of Records*

Records shall be established and maintained to provide evidence of conformity to requirements, and of the effective operation of the Quality (Safety) Management System. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Records shall be maintained to demonstrate the Organisation's conformance with the Management System requirements.

The Organisation shall establish and maintain documented procedures for controlling quality records. Procedures shall include:

* *Identification.*
* *Indexing.*
* *Collection.*
* *Filing.*
* *Easy retrieval.*
* *Safe retention.*
* *Disposal.*

7.8

Examples of quality *(Safety)* records:

* *Log Books.*

* *Cargo Manifests, Bills of Lading, Certificates of Origin, Quality, Quantity, and Mates Receipts.*

* *Training Records.*

* Purchase Orders, Delivery Notes.

* *Approved Suppliers*

* *Ship and Equipment Certificates.*

* *Bunker Records.*

* *Inspection and Test Records.*

* *Internal Quality and Safety Audit Reports.*

* *External Audit Reports.*

All quality (Safety) records shall be retained for a defined period and be readily retrievable. Storage conditions shall preclude loss or deterioration and damage.

Note: Records can be in the form of hard copy, electronic or other suitable media.

5. *Management Responsibility*

Organisation

If the entity that is responsible for the operation of the ship is other than the Owner, the Owner must report the full name and details of such entity to the Administration. [ISM 3.1]

Note: For the purposes of verification, a copy of this report shall be maintained by the Organisation.

5.1 *Management Commitment*

Management Procedures:

The Organisation shall establish and maintain documented procedures for conducting the operation of the Organisation relative to the overall co-ordination of its activities.

The Organisation shall establish and maintain procedures to:

* *Provide guidance to Shipboard Management as necessary, regarding conformance with Policies, new Rules and Regulations and corporate requirements applicable to the intended trade.*

* *Provide adequate resources for manning, administration, equipment and communication;*

* *Provide the Master with problem identification and problem solving techniques and resources.*

Ship Integrity Procedures:

The Organisation shall establish and maintain procedures to ensure:

* *Adequate stability is maintained throughout the voyage.*

* *Watertight and weathertight integrity of the ship.*

* *Ship stress and load criteria are not exceeded.*

Pollution Prevention Procedures: *(See 4.1.1 Note)*

The Organisation shall establish and maintain procedures for the prevention of pollution. These procedures shall be appropriate to the type of ship, cargo and location. Pollution prevention procedures shall include, but are not limited to:

* *Bunkering and oil transfer operations.*

* *Loading and discharging of hazardous cargoes.*

* *Bilge and ballast handling operations.*

* *Disposal of sludge, sewage and garbage.*

* *Emissions to the atmosphere.*

5.2 **Customer Focus**

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction(see 7.2.1 and 8.2.1).

5.3 **Quality *(Safety)* Policy**

Top management shall ensure that the quality *(Safety)* policy:

a) Is appropriate to the purpose of the organisation
b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality *(Safety)* management system.
c) Provides a framework for establishing and reviewing quality *(Safety)* objectives,
d) Is communicated and understood within the organisation, and
e) Is reviewed for continuing suitability.

5.4.2 **Quality *(Safety)* Management System Planning**

The Organisation shall define and document how quality (Safety) requirements for each type of ship it operates will be ensured.

5.5.1 ***Responsibility and Authority*** **[ISM 3.2]**

The responsibility, authority and interrelation of personnel who manage, perform and verify work that significantly impacts on the quality of service, or safety and pollution prevention, shall be defined and documented. Particular attention shall be given to defining the responsibility and authority of personnel that require organisational freedom and authority to:

* *Identify document and initiate action to prevent or control the occurrence of a non- conformity relating to the:*

  * *Safety and Pollution Prevention System.*

  * Service Delivery Process.

  * *Quality (Safety) System.*

* *Be directly involved in the solution of System problems (Corrective Action).*

* *Verify that solutions to problems have been implemented.*

* *Control of non-conforming process until a permanent solution to the problem in the form of a corrective action has been formally implemented.*

* *Review and approve Management System documents.*

Note: *When defining responsibility, authority and interrelation of Organisation personnel, it is recommended that functional titles rather than the Names of the employees assigned to the function be used. This will allow for changes in employee assignments without necessitating a change in documented definitions of responsibility and authority.*

Master's Responsibility and Authority **[ISM 5]**

The Organisation shall clearly define and document the Master's responsibility with regard to:

* *Implementing the Safety and Environmental Protection Policy of the Organisation.*

* *Motivating the crew in the observation of that Policy.*

* *Issuing appropriate orders and instructions in a clear and simple manner.*

* *Verifying that specified requirements are observed.*

* *Reviewing the SMS and reporting its deficiencies to the shore based Management.*

The Organisation shall ensure that the SMS documentation contains a clear statement emphasising the Master's authority. The Organisation shall establish in the SMS that the Master has the overriding authority and the responsibility to make decisions with respect to safety and pollution prevention and to request the Organisation's support where found necessary.

5.5.2 **Management Representative**

Top Management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- Ensuring that processes needed for the Quality *(Safety)* Management System are established implemented and maintained.
- Reporting to Top Management on the performance of the Quality *(Safety)* Management System, and any need for improvement.
- Ensuring the promotion of awareness of customer requirements throughout the organisation.

Note: Responsibilities of the Management Representative may also include liaison with external bodies on matters relating to the Organisation's Quality *(Safety)* Management System.

Designated Person(s) **[ISM 4]**

To ensure the safe operation of each ship and to provide a link between the Organisation and those on board, every Organisation, as appropriate, shall designate a person or persons ashore having direct access to the highest level of Management. The responsibility and authority of the Designated Person or persons shall include monitoring the safety and pollution prevention aspects of the operation of each ship to ensure that adequate resources and shore based support are applied, as required.

The Organisation is responsible for ensuring that adequate resources and shore based support are provided to enable the Designated Person or persons to carry out their functions [ISM 3.3]

Note: The Organisation's Executive Management shall consider potential conflicts of interest when assigning the responsibilities of Management Representative and/or Designated Person.

5.6 ***Management Review*** **[ISM 12.2]**

Top Management with Executive responsibility for quality, safety and pollution prevention shall conduct reviews of the Management System at defined intervals.

The frequency of Management Reviews shall be sufficient to ensure it's suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the Quality (Safety) Management System, including the Quality (Safety) Policy and the Quality (Safety) Objectives.

5.6.2 ***Review Input***

The input to Management Review shall include information on

a. results of audits
b. customer feedback
c. process performance and product conformity.
d. Status of preventative and corrective actions.
e. Follow-up actions from previous management reviews
f. Changes that could affect the Quality (Safety) Management system
g. Recommendations for improvement.

5.6.3 ***Review Output***

The output from the Management Review shall include any decisions and actions related to

a) *Improvement of the effectiveness of the Quality (Safety) Management System* and it's processes.
b) Improvement of product related to customer requirements
c) Resource needs.

Findings, conclusions and recommendations shall be documented as part of the record. The results of Management Reviews shall be brought to the attention of appropriate responsible personnel. [ISM 12.5]

Records of Management Reviews shall be maintained (See 5.6.1).

6 ***Resource management*** **[ISM 6]**

6.1 ***Provision of Resources***

The Organisation shall identify and provide the resources necessary to support and operate ships managed by the Organisation in a manner consistent with the Quality, and the Safety & Pollution Protection Policies and associated objectives. Resources include but are not limited to:

* *Human Resources.*

* *Equipment.*

* *Materials.*

* *Technical Resources*

6.2 ***Human Resources Procedures***

The Organisation shall establish and maintain documented procedures to:

* *Address the selection and recruitment of personnel.*

* *Identify and provide the total staffing requirements for the ship and shore-based operation.*

* *Verify that personnel have appropriate qualifications and experience.*

* *Ensure that there are sufficient trained and qualified personnel to respond to emergency situation.*

* *Identify initial and on-going training requirements (see 6.2.2a).*

* *Familiarise personnel with Safety and Environmental Protection Procedures and Policies.*
* *Provide personnel to carry out Internal Audits.*
* *Establish and maintain job descriptions and qualifications/experience requirements.*
* *Ensure employees are familiar with Organisation Quality (Safety) System.*
* *Appoint personnel and make necessary travel arrangements including emergency travel.*
* *Liase with the ship, the appropriate persons in shore based Management and relevant Third Parties in matters concerning ship's personnel.*
* *Maintain training records of all personnel currently, directly or indirectly employed (see* 6.2.2*).*

Ships Masters **[ISM 6.1]**

The Organisation shall ensure that the Master is:

* *Properly qualified for command.*
* *Fully conversant with the Organisation's Management System including quality and safety.*
* *Given the necessary support so that the Master's duties can be safely performed.*

Ship Crew **[ISM 6.2]**

The Organisation shall ensure each ship is manned with qualified, certificated and medically fit seafarers in accordance with International and National Requirements. The Organisation shall consider statutory onboard manning requirements and also the need to have sufficient personnel available to conduct loading and discharge operations.

Shore Based Personnel

The Organisation shall have suitable qualified and experienced shore based personnel to provide technical assistance and support to onboard Management. The number of personnel and the range of special technical disciplines shall be adequate for the number and range of ship types operated.

Note: *The Organisation shall have a system to control the selection, recruitment and training process when Manning Agents are used. Manning Agents shall be considered as Suppliers (see 7.4.1).*

6.2.2 ***Competence Awareness & Training*** **[ISM 6.3, 6.4 & 6.5]**

The Organisation shall maintain documented procedures to identify training requirements. When determining the training requirements, consideration shall be given to the level of education, previous training and experience of personnel. Records of both internally and externally provided training shall be kept. (See 4.16)

The Organisation shall:

* *Provide training in the Quality and Safety Management System.*

* *Provide training in the use of emergency equipment and procedures.*

* *Ensure personnel are adequately trained and briefed to perform their duties.*

* *Ensure appropriate personnel are familiar with cargo properties.*

* *Provide appropriate onboard familiarisation with ship's machinery, equipment and systems.*

* *Provide training on newly installed equipment.*

* *Ensure personnel have adequate understanding of relevant Rules, Regulations and Guidelines.*

The Organisation shall maintain records of all training.

6.3 **Infrastructure**

The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.

6.4 **Work Environment**

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements.

7 Product Realisation

7.1 Planning of Product Realisation

The organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the quality management system.

7.2 Customer Related Processes

7.2.2 Review of Requirements Related to the Product

The Organisation shall review the requirements related to the product. The review shall be conducted prior to the organisation's commitment to supply a product to the customer. Agreements and Contracts include Marine Management Agreements, Charter Party Agreements and Contracts of Affreightment.

- *Requirements of the Contract are adequately defined and documented.*
- *Any differences between the requirements of the original tender and the Contract are adequately resolved with the Customer.*
- *The Organisation assesses and establishes its capability to fulfil the requirements of the Contract.*

*Records of the results of the review and actions arising from the review shall be maintained (*see 4.2.4)

7.2.3 *Customer Communications*

The Organisation shall designate a specific language for communication. The Organisation shall establish and maintain communication procedures. Communication procedures shall include, but are not limited to, the following:

* *Reporting of the ship's position and situation.*
* *Emergency after hours communications.*
* *Reporting emergencies.*
* *Emergency contacts details.*
* *Distribution of information to, from and within the ship.*
* *Exchange of information between the Organisation, the Customer and the ship.*

* *Reporting arrival and departure information.*

  The Organisation shall establish and maintain communications procedures that ensure the Customer receives:

* *Information regarding the ship's operation or availability that will affect the service.*

* *Routine reports and documents as agreed between the parties.*

7.3 **Design & Development**

The scope of ISM does not include Design & Development and therefore does not require to be addressed.

7.4 **Purchasing**

7.4. 1 **Purchasing Process**

The organisation shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependant upon the effect of the purchased product on subsequent product realisation or the final product.

The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the organisation's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluations shall be maintained. (see 4.2.4)

Purchased products or services that may affect quality include but are not limited to:

* Ship stores, fuels, lubricants, equipment and spare parts.
* *Technical and Safety Services.*
* Ship Repair Services.
* Towage Services.
* Stevedoring and Tallying Services.
* Manning Agents.
* Surveyors.
* Port Agencies.
* Pilotage Services.
* Classification Services.

7.4.2 **Purchasing Information**

Purchasing information shall describe the product to be purchased, including where appropriate

a) Requirements for approval of product, procedures, processes and equipment,
b) Requirements for qualifications of personnel

The type, class, style, grade model and serial number.

Pertinent issues of specifications, drawings, processes and inspection requirements.

Requirements of approval or qualification of products, procedures or services.

The qualifications, certifications, and/or license requirements of personnel providing a service.

Requirements for conformance with applicable Quality System Standards including title, number, and/or issue of the applicable Standards.

The Organisation shall review and approve quality related purchasing documents prior to release, in order to ensure that purchasing data is properly defined and complete.

The Organisation shall define approval procedures for necessary substitutions which meet required specification place of delivery and delivery times.

7.4.3 **Verification of Purchased Product**

The organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation shall state the intended verification arrangements and method of product release in the purchasing information.

Ship construction and repair facilities represent an example where verification of products or services are performed at a supplier's facility. Verification requirements for products or services provided shall be specified in the ship construction or repair specification.

Inspection of a service may include establishing the credentials of the individuals performing a service aboard the ship (i.e., verification of a Welder's certification to perform a particular welding procedure aboard the ship). Requirements for purchased products or services shall be specified on the purchasing documents.

* Spare parts shall be inspected for conformance with requirements before being incorporated into ships complement of spares.

* Fuel oil analysis shall confirm conformance of received fuel oil with requirements prior to use.

* Service technician's capability shall be verified prior to performing Suppliers repairs or service.

* Nominated personnel shall verify acceptability of voyage repairs to critical equipment.

* Shipyard repairs of critical equipment shall be verified prior to leaving the shipyard.

7.5 ***Production and Service Provision*** **[ISM 7]**

7.5.1 ***Control of Production and Service Provision***

The Organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions include:

* *Documented procedures defining ship and shoreside operations where the absence of such would adversely affect quality and/or safety and pollution prevention.*

* *Conformance with applicable Flag State, Port State and International Resolution, Codes and Requirements.*

* *Conformance with applicable Classification Requirements.*

* *Suitable maintenance of propulsion, navigation and cargo handling equipment.*

* *The use of technically fit equipment to provide for transportation requirements.*

* *Criteria for monitoring of loading, transfer, discharge and transportation of cargo.*

These activities shall be assigned to and performed by qualified personnel. [ISM 7]

Deck Operations:

Deck operations shall be conducted in accordance with Organisation and Industry Guidelines. The Organisation shall consider documented procedures for, but not limited to, the following activities:

* *Mooring and anchoring operations.*

* *Port, cargo, fire, and security watches.*

* *Pilot embarkation/disembarkation.*

* *Preparation for arrival and departure.*

* *Pre-cargo operations safety and equipment checks.*

* *Watch keeping duties.*

* *Emergency procedures.*

* *Loading, discharge, transfer and ballast operations.*

* *Handling of special and hazardous cargoes.*

* *Control of spillage including oil and hazardous materials.*

Engine Room Operations:

Engine room operations shall be conducted in accordance with Organisation and Industry Guidelines. The Organisation shall consider documenting procedures for, but not limited to, the following activities:

* *Watchkeeping, main engine and auxiliary plant operation.*

* *Bunkering, transfer and treatment.*

Planned and Preventive Maintenance:

The Organisation shall establish and maintain a preventive Maintenance Programme to ensure the operational reliability of equipment affecting quality, safety and pollution prevention. The preventive Maintenance Programme shall ensure the ship and equipment is maintained in accordance with current Rules, Regulations and Organisation requirements. The Organisation shall consider documenting procedures for, but not limited to, maintenance of: [ISM 10.1 & 10.4]

* *Mooring equipment.*

* *Cargo handling, control and associated equipment.*

* *Navigation equipment.*

* *Main engine and auxiliary plant.*

* *Safety and fire fighting equipment.*

* *Hull and associated equipment and fittings.*

In establishing the above procedures, instructions and recommendations of the equipment Supplier or Maker and the Organisation's operating experience shall be considered.

The Organisation shall ensure that inspection of the ship and equipment is performed at appropriate intervals (see 4.10). [ISM 10.2.1]

Non-conformances shall be reported, controlled and effectively corrected (see 4.13 & 4.14).

Navigation Procedures:

Ship Navigation shall be conducted in accordance with Organisation and Industry Guidelines. The Organisation shall consider documenting procedures for, but not limited to, the following activities:

* *Bridge watch keeping duties, voyage planning and bridge organisation.*

* *Navigation in confined waters.*

* *Navigation in reduced visibility.*

* *Blind pilotage.*

* *Organisation and Master's standing orders.*

* *Operation of navigation equipment.*

* *Chart and publication correction.*

* *Manoeuvring characteristics.*

* *Navigation in separation schemes.*

Safety Procedures:

The Organisation shall establish and maintain documented procedures for potentially hazardous shipboard operations. Safety procedures may form part of other operational procedures contained in other Manuals. The following are examples of safety procedures:

* *Permit to Work Systems.*
* *Working in hazardous conditions.*
* *Entry into confined spaces.*
* *Use of protective clothing and equipment.*
* *Handling and storage of hazardous materials.*

Emergency Preparedness **[ISM 8]:**

The Organisation shall establish and maintain documented procedures for identifying, reporting and responding to potential emergency situations. Emergency procedures, shall provide for a programme of drills and exercises to prepare for emergency actions. The Management System shall ensure that the Organisation can respond at any time to hazards, accidents, incidents and emergency situations. Emergency preparedness procedures shall as a minimum include:

* *Fire and boat drills.*
* *Use of emergency equipment.*
* *Emergency steering drills.*
* *Emergency medical procedures and evacuations.*
* *Confined space rescue.*
* *Oil spill response procedures.*
* *Search and rescue procedures.*
* *Shore emergency response plans.*
* *Hazardous substances clean-up.*
* *Total loss of power.*
* *Towage and salvage procedures.*
* *Flooding.*

7.23

Ship's Business:

Ship's business shall be conducted in accordance with Organisation and Industry established and accepted practices. The Organisation shall consider documenting procedures for, but not limited to, the following:

* *Operations, Chartering and Post Fixture procedures.*

* *Appointment of Agents.*

* *Trading and Class Certification of ships.*

* *Ship's Disbursements*

* *Insurance and Claims procedures.*

Technical Procedures:

The Organisation shall establish and maintain documented procedures for gathering information about applicable Rules, Regulations, Codes, Guidelines and Standards and arrange for their conformance. Technical support shall include the review of new requirements.

The Organisation shall establish and maintain procedures to:

* *Ensure maintenance, repairs and relevant surveys are conducted in a timely manner with respect to the ship's trade, cargo, crew and passengers.*

* *Provide technical reports at predetermined intervals on the operational capability of the plant, machinery and equipment.*

* *Communicate the status of the ship to all interested parties in the event that special conditions or limitations affecting the intended trade or operational parameters become apparent.*

The Organisation shall establish and maintain procedures for documenting ship repair/dry dock specifications.

7.5.3 ***Identification and Traceability***

The Organisation shall establish and maintain documented procedures for the identification of ship status at any point in the voyage. Ship status identification may include:

* *Ship Schedules and Situation Reports.*
* *ETA - Estimated time of arrival.*
* *ETD - Estimated time of departure.*
* *Notice of readiness.*

The Organisation shall establish and maintain documented procedures for the preparation and maintenance of Cargo Plans, Manifests, Bills of Lading in order to identify:

* *Cargo type, origin, quantity, condition.*

* *Cargo Owner.*

* *Cargo location aboard ship.*

* *Port of loading.*

* *Port of discharge.*

Permit for work systems shall include positive methods of identification of "safe to work" conditions. Positive methods to prevent unsafe working conditions once work has started shall be employed (i.e. equipment, labels, marks, tagouts and lockouts).

7.5.4 **Customer Property**

The organisation shall exercise care with customer property while it is under the organisation's control or being used by the organisation. The organisation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.(see 4.2.4) Customer property includes, but is not limited to:

* *The ship.*
* *Fuel oil.*
* *The Charterer's cargo.*
* *Cargo handling equipment.*
* *Information manuals, ships plans.*

Note: *Verification by the Organisation does not absolve the Customer of the responsibility to provide acceptable products and/or information.*

7.5.5 ***Preservation of Product***

The service process of Ship Management, and Marine Transportation does not generate a tangible product that can be handled, stored, packaged, preserved or delivered. Therefore this section does not apply to Ship Management and Marine Transportation.

7.6. **Control of Monitoring and Measuring Devices**

The organisation shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1)

The organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measurement equipment shall:

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) Be adjusted or re-adjusted as necessary;
c) Be identified to enable the calibration status to be determined;
d) Be safeguarded from adjustments that would invalidate the measurement result;
e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained. (see 4.2.4)

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8.2.2 ***Internal Audits*** **[ISM 12.1 & 12.3]**

The Organisation shall establish and maintain documented procedures for Internal Quality and Safety Audits. Procedures shall include:

* *Planning and scheduling Internal Quality and Safety Audits.*

* *Performing Internal Quality and Safety Audits.*

* *Reporting and actioning Quality and Safety Audit results.*

* *Maintenance of Internal Quality and Safety Audit Records. (See 4.2.4)*

Internal Audits of Management System activities shall be scheduled based upon the impact of the activity on quality, safety and pollution prevention.
Appropriate responsible personnel shall be informed of the results and Internal Audits. Appropriate corrective action shall be taken in a timely manner in response to non-conformances discovered during an Internal Audit [ISM 12.5 & 12.6].
Internal Audit follow-up shall be performed to ensure corrective actions have been implemented and are effective.

Internal Audits shall be carried out by persons independent of the areas being audited [ISM 12.4].

8.2.3 **Monitoring and Measurement of Processes**

The organisation shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 **Monitoring and Measurement of Product**

The organisation shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements.(see 7.1)

The Organisation shall establish and maintain documented procedures for performing inspections and tests to verify that requirements for quality, safety and pollution prevention are met.

Requirements for quality shall include those requirements specified or implied in any Agreement i.e. Charter Party, Ship Management Agreement, Purchase Order or Service Contract.

Requirements for safety and pollution prevention include appropriate measures for ensuring the operational reliability of equipment, the sudden operational failure of which could result in a hazardous situation. [ISM 10.3]

The Organisation shall maintain records of inspections and tests performed. The records shall clearly show conformance of the service processes with Contractual requirements. Examples of inspection and test records are:

* *Cargo Quality/Quantity Certificates.*

* *Bunker Analyses Reports.*

* *Equipment Calibration Certificates.*

* *Trading and Class Certificates and Records.*

* *Log Books.*

* *Critical Equipment Inspection and Test Records.* ***[ISM 10. 2.4]***

Charter Party Agreements

The Organisation shall identify inspections, measurements and tests required to verify service conformance with requirements (both specified and implied) of the Charter Party Agreement. Charter Party Agreements frequently include, but are not limited to, requirements concerning:

* *Maintenance of cargo temperature limits.*

* *Maintenance of cargo pressure limits.*

* *Cargo handling rates.*

* *Cargo tank or cargo hold condition.*

* *Ship performance criteria.*

Ship Management Agreements

The Organisation shall identify inspections and tests necessary to verify conformance with the requirements of the Ship Management Agreement. Ship Management Agreements frequently include, but are not limited to, requirements concerning:

* *Capable and experienced crew.*
* *Fuel oil specifications.*
* *Ship's structure maintenance criteria.*
* *Ship's equipment maintenance criteria.*
* *Suitable and adequate spares and stores.*
* *Accounts, budgets, advances and reports.*

Safety and Pollution Prevention

The Organisation shall identify inspections and tests necessary to verify conformance with safety and pollution prevention system requirements. The safety and pollution prevention requirements may include, but are not limited to, requirements concerning: [IMO 10.2.1]

* *Emergency equipment inspections and tests.*
* *Inventory of Dispensary.*
* *Safety and lifesaving equipment and rations inventory.*
* *Alarm and emergency shutdown tests.*
* *Cargo and fuel systems integrity inspections and tests.*
* *Pre-arrival / departure safety and equipment checks.*
* *Safety Audits.*

8.3 ***Control of Non-Conforming Product or Service*** **[ISM 9. 1]**

The Organisation shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with non-conforming product shall be defined in a documented procedure. Controls include:

* *Identification.*
* *Documentation.*
* *Evaluation.*
* *Disposition.*
* *Notification of appropriate personnel.*

Examples of non-conformities may include:

* *Near misses.*
* *Hazardous situations.*
* *Insurance claims.*
* *Failure of a Management System element.*
* *Receipt of Note of Protest.*
* *Failure of documented procedure to meet operational requirement.*
* *Cargo care parameters out of specification (i.e. temperature, pressure).*
* *Failure to fulfil Contractual requirements (Charter Party, Marine Management Agreement, Contract of Affreightment).*
* *Customer complaint.*

8.5 Improvement

8.5.1 Continual Improvement

The organisation shall continually improve the effectiveness of the quality management system, through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions and management review.

8.5.2 + 8.5.3 *Corrective and Preventive Action* [ISM 9.0]

The Organisation shall establish and maintain documented procedures for implementing corrective and preventive action. The Organisation shall define the responsibility and authority for instituting correction and preventive action.

The implementation of corrective and preventive action shall begin with the detection of an actual or potential System related problem. Corrective and preventive action shall be taken to eliminate the causes of actual or potential non-conformances. Action taken shall be shown to be effective to prevent recurrence.

Corrective and preventive action may result in changes to controlled processes, documented procedures, training requirements and equipment.

The Organisation shall implement corrective and preventive actions and revise existing documents to reflect the action.

Procedures for corrective action may include:

* *The effective handling of legitimate Customer complaints.*
* *Performing and recording an investigation to determine the root cause of the non-conformance.*
* *Determining the corrective action needed to eliminate the cause of the non-conformance.*
* *Follow-up to ensure the corrective action is implemented and effective.*

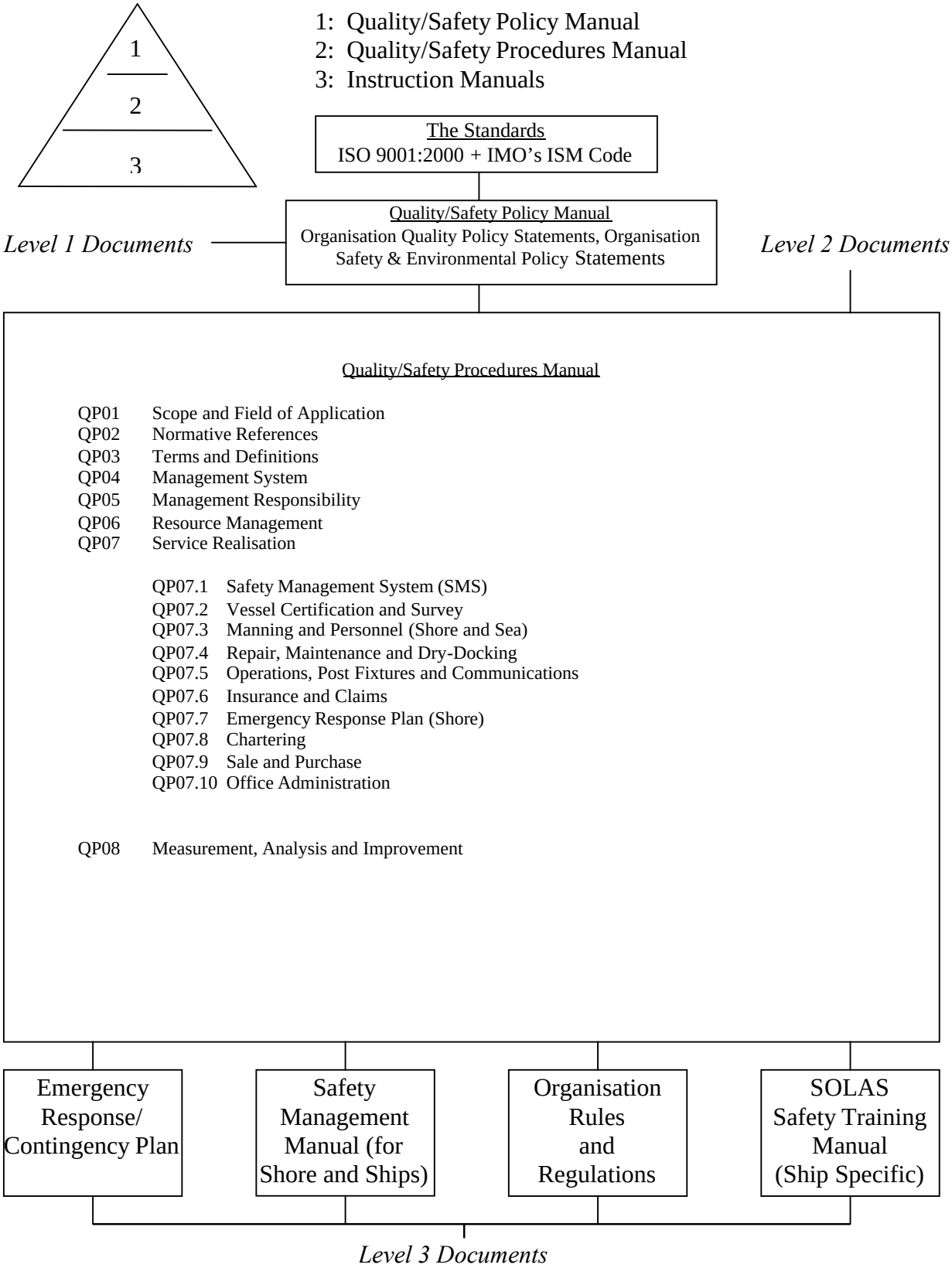


Figure 6A - Proposed Documented Quality/Safety System

The SOLAS Safety Training Manual

Under SOLAS 1974 Chapter III, Part B Regulation 18, sub-section 2, a training manual complying with the requirements of Regulation 51 shall be provided in each crew messroom and recreation room or in each crew cabin.

SOLAS Chapter III, Part C Regulation 51 states that the training manual which may comprise of several volumes, shall contain instructions and information, in easily understood terms and illustrated wherever possible, on the lifesaving appliances provided in the ship and on the best methods of survival. Any part of such information may be provided in the form of audio-visual aids in lieu of written material.

It is vital that this information is ship specific; and that the reading of this manual forms part of the familiarisation routines - particularly for crew who are new to that specific ship. All crew will be asked to sign that they have read and understood the manual.

The following would, where appropriate, be described in detail:

- method of donning of lifejackets and immersion suits, as appropriate
- mustering points, assigned stations etc.
- boarding, launching and clearing survival craft and rescue boats
- method of releasing and launching the survival craft
- use of devices for protection in launching areas, where appropriate
- illumination in launching areas
- use of all survival equipment; detection equipment, radio life-saving appliances use of drogues
- use of engine and accessories
- recovery, stowage and securing of survival craft and rescue boats
- the dangers of exposure
- how to make optimum use of survival facilities
- various methods of retrieval (helicopter/shore/ship's line throwing apparatus)
- emergency instructions
- emergency repair of life-saving appliances

PART 8
THE AUDIT PROCESS

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THE AUDIT PROCESS

Once a Quality Management System has been established and implemented the only possible way an Organisation can verify the effectiveness of the System is to carry out regular Audits. It will be necessary, therefore, to develop a capability to manage the entire process. This Audit function should be independent from and have no direct responsibility for the implementation of the Quality System elements.

AUDIT OBJECTIVES

The objectives of an Internal Audit are:

* To determine the implementation and effectiveness of one's own Quality System.
* To determine conformance or non-conformance of Quality System elements to specified Contractual requirements.
* To provide a basis for improvement of a Quality System.
* To meet Regulatory requirements.
* To achieve Second or Third Party Registration.

The objectives of an External Audit are:

* To evaluate a potential Supplier with a view to establishing a Contractual relationship.
* To verify that a Supplier's Quality System continues to meet specified requirements and is being effectively implemented.

THE RESPONSIBILITY FOR AUDITING

In earlier sections of the Course documents it has been emphasised that one of the responsibilities of the Quality Assurance Department is to undertake Internal or External Audits. Any such Audits should not result in transferring the responsibility for the achievement of quality from operating staff to the auditing function.

In the very small Organisation, the responsibility for auditing may rest with the Senior Executive. After all, the Senior Executive has the ultimate responsibility for Quality and the Quality Systems have been developed by him/her in conjunction with the Company's Senior Management and, therefore, he/she should be aware of the efficiency of the Organisation.

There is a requirement for a Company to be aware of its financial status and an Audit is carried out to verify that a Company's Accounting System is in order and that the results are accurate. With a Financial Audit, however, this is undertaken as a legal requirement under the Companies Act. The results do identify a Company's profit and loss position and a Company's Board of Directors will act on the results. The "bottom line" is the spur.

WHY AUDIT?

A Company's Quality System is not generally seen in the same light as the Financial Accounting System, yet, because of inefficient control over all its activities, a Company could well be losing a great deal of money. The inefficiencies due to duplication of activities, high repair and scrap rates, malpractices and so on, may result in the quality costs (the costs of putting things right) being higher than the overall profit margin.

A Quality Audit, if effectively undertaken, should uncover such problems, providing the Audit is carried out against documented requirements and by trained and qualified personnel.

WHAT IS AN AUDIT?

(All Clauses refer to ISO 9000:2000)

All Quality System Standards call up a requirement for the auditing or the review of the Quality System and, in general, such an activity could be defined as:

A systematic, independent and documented **Process** (Clause 3.4.1.) for obtaining **Audit Evidence** (Clause 3.9.4.) and evaluating it objectively to determine the extent to which **Audit Criteria** (Clause 3.9.3.) are fulfilled.

NOTE: Internal Audits, sometimes called First Party Audits, are conducted by, or on behalf of, the **Organisation** (Clause 3.3.1.) itself for internal purposes and can form the basis for an Organisation's self declaration of C**onformity** (Clause 3.6.1.)

External Audits include what are generally termed "Second" or "Third Party Audits".

Parties having an interest in the Organisation, such as Customers, or by other persons on their behalf conduct second Party Audits.

Third Party Audits are conducted by external independent Organisations. Such Organisations provide Certification or Registration of conformity with requirements such as those of ISO 9001 and ISO 14001:2004.

When Quality and Environmental **Management Systems** (Clause 3.2.2.) are audited together, this is termed a "Combined Audit".

When two or more auditing Organisations co-operate to Audit a single **Auditee** (Clause 3.9.8.) jointly, this is termed a "Joint Audit".

AUDITING 9001:2000

It should be understood that a Quality Management System (QMS) is that part of the organisation's management system that focuses on the achievement of outputs (results), based on the quality objectives, to satisfy the needs and expectations of its customers.

In the previous version of the standard the requirements for a documented QMS were formatted in a department/hierarchical manner whilst in the 2000 version there is a very strong emphasis on a Process Model Approach. Fundamentally this is to encourage a far greater appreciation of the fact that ALL activities of the Company CAN impact on quality performance either directly of indirectly and therefore, that the role, importance and methods of work of ALL departments should be defined and managed.

THEORETICAL AUDITING THE PROCESS AND THEIR INTERACTIONS

We audit a QMS using the process approach; the audit should provide us with the answers to certain questions:

A) Have the processes been identified and established?
B) Have the processes been appropriately described in procedures?
C) Are the interactions between processes defined, controlled and managed?
D) Are the required results enabled by each of the processes?

When we have the answers to these questions, we can then establish the results of the audit and determine the auditor recommendations.

By using the process approach when auditing 9001:2000 we have to not only Audit individual department/function/activity conformance with requirements BUT ALSO Audit and evaluate the effectiveness of that department/function/activity in relation to its impact on the overall "chain of events" designed to achieve Customer Satisfaction.

AUDIT DEPTH, SCOPE AND TYPE

As has already been stated, there is a requirement to seek objective evidence to determine that an activity has been carried out in accordance with specified requirements. These specified requirements are the Procedures and Job Instructions. Initially, however, immediately after establishing a Quality System, an Audit should be carried out to confirm that all the relevant Procedures and Instructions are available at the activity locations and that personnel are aware of their responsibilities within the System. In project-related industries this would be undertaken at the commencement of each project. The objectives of such an Audit are to confirm the existence and validity of the necessary Quality System. Such an Audit is known generally as a System Audit.

Depth of Audit

The System Audit is, therefore, a superficial or "shallow" Audit and can be utilised very effectively to get the "feel" of a Quality System.

In order to confirm whether or not a Procedure or Job Instruction is actually being implemented and is effective, an "Adherence" or "Conformance" Audit is carried out. This "Adherence' or "Conformance" Audit is a "Deep" Audit. It gets down to the nitty-gritty so to speak.

Scope of Audit

The "Scope" of an Audit relates to the amount of the Quality System that should be reviewed to confirm that the activities are in conformance with requirements.

In the case of Internal Activity, Management, together with the quality function, will determine which Quality System elements; Procedures and Instructions are to be audited within a given time-scale.

Externally, the Customer will make this decision. In any event, the Auditee/Assessee should be consulted when determining the Scope of the Audit or Assessment.

Type of Audit

The scope and depth of an Audit are variable factors, which have to be considered in detail during the preparation and planning of audits. The type of Audit is determined by who is performing the Audit and the location of the Auditee, and can be either an Internal or External Audit.

A **First Party Audit** is an Audit carried out by a Company to evaluate its own performance (Internal Audit). The notification procedure and the conduct of the Audit are not quite as formal as for an External Audit.

A **Second Party Audit** is an Audit carried out by a Company to evaluate the activities of its Contractors, Suppliers, Agents, Licensees, etc. The notification procedure and procedure for the conduct of the Audit are more formal and necessitate more planning and preparation than for the Internal Audit.

A **Third Party Audit** is an Audit carried out by a Customer, Third Party Organisation, Regulatory Authority, etc., on a Company to assess its activities against specific requirements. It is an Audit carried out by External Sources on your own Organisation.

A Third Party Audit would normally not be addressed by an Audit Procedure but by a Job Instruction, which should describe how the Company will deal with such an Audit. Such a Job Instruction could well include:

* The requirement to advise relevant employees of the objectives and scope of the Audit/Assessment.
* The appointment of suitable members of staff to accompany members of the Audit/Assessment Team (generally known as Escorts).
* The provision of resources for the Audit Team (Office accommodation, telephone, copy facilities and others).
* The requirement to provide access to facilities and objective evidence as requested by the Audit Team members.
* The requirement to co-operate with the Audit Team members to permit the Audit/Assessment objectives to be achieved.
* The necessity to determine and implement corrective action based on the Audit results.

AUDIT/ASSESSMENT SCHEDULING

The need to perform an Audit/Assessment should be determined taking into account the maturity of the system, specified or regulatory requirements and any other pertinent factors.

In the case of External Audits, significant changes in Management, Organisation, Policies, techniques or technologies could well affect the System and would need to be verified. Changes to the System itself and the results of previous audits are other circumstances, which should be considered when deciding Audit frequency.

Internally, audits are organised on a regular basis to verify the implementation and effectiveness of one's own System and to review the results of any significant changes as described above.

In both the external and internal situations it is important to establish an Audit/Assessment Schedule.

The Audit Schedule - This should be established as soon as possible after a Quality System is implemented. It is recommended that a System Audit be undertaken within four to six weeks of implementation and then conformance audits scheduled to commence immediately thereafter. The System Audit could identify areas of concern, which should be used to establish priorities for future audits.

A typical schedule is shown on page 8.37. This schedule can be utilised for both internal and external activities.

THE AUDIT PROCESS

Audits, like most other activities, require considerable preparation and planning, which should take into consideration the following:

* The scope and objectives of the Audit/Assessment.
* The identification of the Auditee's/Assessor's personnel who have significant responsibilities regarding the scope and objectives.
* The identification of reference documents such as the applicable Quality System Standard, Quality Manual, Procedures, Job Instructions, Contract Work scope and others.
* The identification of Audit/Assessment Team members.
* The language of the Audit/Assessment.
* The place, date and time where the Audit/Assessment is to be conducted.
* The identification of the organisational functions, or system elements, to be audited or assessed.
* The anticipated time and duration for each activity.
* The development of Checklists.
* The format and distribution of the Audit/Assessment Report.

The Total Audit Process could, therefore, be considered as having four distinct phases, which are:

* Preparation and Planning.
* Performance.
* Reporting.
* Follow-up.

The only phase of the Total Audit Process discernible to the Auditee is "Performance". This phase generally consumes only thirty per cent of the total activity. As a rule of thumb, the four phases in total could be calculated quite simply using the following percentages - 50% of the time devoted to Preparation and Planning, 30% to Performance, 10% to Reporting and 5% to follow-up. These percentages are basic only and cannot be taken as definitive and they have been found to be reasonably accurate from experience. It is, therefore, important to evaluate initially the time taken in the performance activity in discussions with the Auditee and/or a Pre-Audit Visit and to calculate the total time accordingly.

PREPARATION AND PLANNING

This phase of the Audit Process is itself divided into six subsidiary activities as follows:

1. Appoint a person or persons to be responsible for the Audit.
2. Notify the Auditee.
3. Agree the Audit Timetable.
4. Identify, obtain and review all relevant documentation.
5. Brief the Audit Team members.
6. Develop the Audit Checklists.

A review of each of these activities is to be considered in detail:

1. Appoint a person or persons to be responsible for the Audit - About two weeks prior to a scheduled Audit/Assessment, the Quality Manager should formally assign a person to be responsible for the Audit Process. This person is normally a member of the quality assurance function and may even be the Quality Manager himself. The Auditor would be advised of the date scheduled for the Audit, the organisation, department or discipline to be audited, the names of the persons to contact and the scope and objectives of the Audit.

Once nominated, the Auditor becomes responsible for planning, preparing, performing and reporting the Audit. Should the scope of the Audit necessitate the use of more than one person, i.e. an Audit Team, and then the Auditor becomes the Team Leader and will be responsible for briefing the Team and controlling the Audit.

The individuals selected as Audit Team members need not be from the quality assurance function. They should, however, have undergone training and indoctrination in auditing techniques and should not have direct responsibility for any of the work in the areas to be audited.

2. Notify the Auditee - This should be done in writing with at least seven days notice of the intention to conduct an Audit. Initially, the Auditor (or Team Leader in the case of Major Audits) should informally contact the Auditee to confirm the scheduled date and to discuss the Audit Scope. Confirmation of all such discussions should be made formally.

In the case of Internal Audits, the notification would normally be in the form of an Internal Memo and should include, as a minimum, the following information:

* Date and time of Audit.
* Audit scope and objectives.
* Name(s) of Auditor(s).
* Request to advise if date and time should not be convenient.

Externally the formal notification would be much more detailed and should include, as a minimum, the following information:

* Date and time of Audit.
* Audit scope and objectives.
* Name(s) of Auditor(s).
* Audit timetable or itinerary.
* Invitation to Senior Management to attend both Entry and Exit Meetings.
* Request for Escorts to be available to accompany each member of the Audit Team.
* Request for Office and other facilities to be made available.
* Request to confirm the arrangements (RSVP).

Having made the formal notification, then all relevant information relating to the activities or functions to be audited should be obtained.

3. Agree the Audit Timetable - This should be done in conjunction with the Auditee. The timetable should be planned to be most effective and to avoid involving too many people. It is considered good practice to plan to commence Audit proceedings at least half an hour after the Auditee's commencement of work. This gives time for the Auditee to prepare for the day's work and to allocate responsibilities to those not involved in the Audit.

A late finish should be avoided where possible as the Auditee could have other pressing matters to attend to, the concern for which may make the Auditee less attentive to the Audit.

4. Identify, obtain and review all documentation relative to the Audit - This refers to documents such as procedures, job instructions, inspection and test plans, specifications, and so on. If a previous audit has already been carried out, then the report of that Audit should form part of this documentation. There may be corrective actions still outstanding, which should be followed up. Once all relevant information has been reviewed the next step should be to:

5. Brief Audit Team members - The Audit Team Leader would be accountable for briefing the Team members as to their responsibilities within the Audit. The Team Leader assumes total charge of the Audit and must ensure that all Team members are aware of the part they must play. At this juncture he/she would allocate Audit tasks to the Team members based upon their areas of expertise and would assign to them the appropriate documentation. Each Team member should then review the documentation and develop their own Checklists.

6. Develop an Audit Checklist - A Checklist is not a mandatory exercise but it is strongly recommended. In developing a Checklist, the Auditor would be required to read all the relevant documents in depth. This should then make the Auditor familiar with the Auditee's activities, which would lead to a greater understanding between the two parties. A Checklist also acts as an aide-memoir and governs the continuity and depth of the Audit.

Many Organisations utilise standard Pre-prepared Checklists but the use of these generally results in the Audit becoming a mechanical exercise on the part of the Auditor, with the Auditee becoming little more than an answering machine.

ROLES AND RESPONSIBILITIES

The roles and responsibilities of the audit/assessment team are summarised below:

Auditor

Auditors should be responsible for:

- Complying with the audit criteria
- Planning and carrying out assigned responsibilities competently
- Communicating and clarifying audit requirements
- Documenting the objective evidence
- Reporting audit results
- Verifying, as required, the implementation and effectiveness of corrective action
- Retaining and safeguarding documents relevant to the audit.
- Ensuring the confidentiality of the audit results
- Co-operating with, and supporting the team leader

Audit team leader

The audit team leader is totally responsible for all phases of the audit, and for the conduct of the team under his/her leadership. The team leader should have management capabilities and experience, and should have the responsibility and authority to make final decisions regarding the conduct of the audit, and of any observations.

The audit team leader should also have the responsibility to:

- Assist with the selection of team members
- Prepare the audit itinerary
- Submit the audit report
- Direct follow up actions as required.

DOCUMENT REVIEW

It would be beneficial, if economically viable, for the Audit Team Leader to make a Pre-Audit Visit to the Auditee to establish these matters. The Team Leader would, in effect, "walk the job" and as a result would be able to determine the number of people and the time required to undertake the Audit. The results of the visit being confirmed as above.

When developing Checklists for the Audit of procedural activities (the Adherence or Conformance Audit) care should be taken not to include items, which would not produce objective evidence. The procedure for auditing should give the Auditor the flexibility to determine whether an activity is acceptable or not rather than a strict YES or NO. There are some instances where an activity may not be strictly in accordance with procedure but may otherwise be perfectly acceptable. It is, therefore, prudent to denote acceptability and qualify the result.

The auditing of the way in which the Company has effectively, appropriately and completely defined the Process and Interactions within the Organization is essentially a two (2) stage activity. The first stage occurs during Audit Preparation in **Document Review** whilst the second stage – verification - occurs during the Site Audit itself.

In preparing to Audit an individual part of an overall process an Auditor should ensure that the documentation presented can and does:

- Identify the purpose of the process.
- Identify the inputs.
- Identify the intended outputs.
- Establish the flow (sequence of activities).
- Identify resources used.
- Identify what controls are in place (procedures, instructions, specifications, etc).
- Identify what planned monitoring arrangements are required.

Auditors must be aware that the outputs may not be limited to the useful or intended outputs but may also include unintended by-products. Auditors have to be aware that the processes do interact and the outputs from some processes do constitute the inputs into others and also may be controlling them.

Therefore X Checking between different documents within the overall system to ensure the consistency and completeness of the output of one "Procedure" and the input of another should be a requirement. Document Review against 9001:2000 should not be a case of "reading one procedure at a time in isolation of the others".

The document Review would be carried out in conjunction with the preparation of Checklists.

As with all management systems the QMS documentation reflects the way each individual organisation operates to meet the stated requirements of ISO 9001: 2000. Because the standard takes a process approach, it becomes important that the auditor understands how the system works and how the various inter-relationships between each function and process work.

The Document Review is extremely important as the auditor has not only to verify the adequacy of the documented system in its content to meet the requirements of the standard, but also that the intent of the requirements is addressed.

ISO 9001:2000 – Clause 4.1 – "the organisation shall establish, document, implement and maintain a QMS and continually improve its effectiveness in accordance with the requirements of this (ISO 9001) International Standard."

So as an auditor, even before we start the on-site audit, we have to decide whether the documented system, as presented by the organisation, is able to satisfy this requirement.

We would, as a minimum, expect to see the following documents submitted, although the layout and format will vary greatly from company to company.

- A Quality Policy.
- A Quality Manual.
- Procedures expressly required by the Standard.
- Other documents as appropriate and a listing of other system documents not provided.

With this documentation to hand the lead auditor and his team (if appropriate) can conduct the document review and should be able to establish the following:

a) Establish the scope of the organisation and if any permissible exclusions are claimed from section 7 of the ISO 9001:2000, evidence of the exclusion's justification must be available and this must be consistent with the stated scope of the company.

b) Verify that the organisation has met the requirements of 4.1 (a) and 4.1 (b). Have they correctly identified all of the processes that are required for their QMS, and has the sequence and interaction between these various processes been correctly mapped and understood?

c) Establish that all the specific requirements of the standard have been addressed the documented system. It is important to remember that the layout of the system is up to the individual organisation and while it may not be to the liking of the auditor it may well fit the style of the company very well. It is, however, common to see each requirement of the standard addressed by an individual procedure.

d) Does the Quality Policy meet the requirements of the standard; but just as important, is it really appropriate with regard to the purpose of the organisation, its commitment to continual improvement and does it set a framework for establishing quality objectives.

e) The auditor has to decide if the theoretical capability of the organization as detailed within the system creates the continual improvement of the QMS processes as required by the standard.

It may well prove to be advantageous to carry out the document review at the organisation's office, with access to the Quality Management Representative (QMR) to ensure the auditor fully understands the processes and interactions of the organization within the QMS.

The auditor will issue a report on the Document Review including the conclusion and any NCRs or observations raised. As with all NCRs it is important that they are clearly written so that the organization is able to readily understand the nature of the problem and thus determine what corrective actions are appropriate.

PERFORMANCE OF THE AUDIT

As for preparation and planning (Phase 1), the Performance Phase is subdivided into a number of distinct activities. There are four in all but these should not be confused with the four phases of the Total Audit Process. They are:

1. The Entry Meeting.
2. The Audit itself.
3. Evaluation of results.
4. The Exit Meeting.

1. The Entry Meeting - Upon arrival at the Audit venue, the Auditor (or Audit Team Leader) should convene a brief meeting between the Auditor and the Auditee. This meeting is given many titles such as an Entry Meeting, Entry Interview, Pre-audit Meeting, Opening Meeting and others.

The purpose of an Entry Meeting is to:

* Introduce the Auditor (or Audit Team) to the Representatives of the Auditee, if they are not already known to each other.
* Confirm briefly the purpose and scope of the Audit.
* Review the Audit scope, timetable and agenda.
* Provide a short summary of the methods and procedures to be used to conduct the Audit.
* Clarify any ambiguities of the Audit Process.
* Introduce the method by which any non-conformances will be addressed (i.e. the corrective action request).
* Agree a tentative time for the Closing Meeting and invite Senior Management of the Auditee to attend.
* Arrange for Escorts to accompany the Audit Team.
* In the case of External Audits, confirm that suitable Office facilities and resources will be made available to the Audit Team.
* Arrange to undertake a familiarisation tour of the facility, if time permits.

The Names of those present should be recorded. An Attendance Register (page 8.42) is a suitable document for this. It should be stressed, however, that Names and positions should be printed to retain legibility.

2. The Audit itself - This should be conducted using the prepared Checklists as a guide. These Checklists could be expanded, if necessary, to determine conformance with specified requirements and/or determine the effectiveness of the implementation of a system's element.

Auditing against the standard has to not only Audit individual department/function/activity conformance with requirements BUT ALSO audit and evaluate the effectiveness of that department/function/activity in relation to its impact on the overall "chain of events" designed to achieve Customer satisfaction.

A Process Audit is essentially a Vertical Audit where an Auditor would follow the process from one end to another verifying the effectiveness of control arrangements. In auditing processes, Auditors should however not limit themselves to merely determining conformance of the activities (actions performed) but should be able to assess that the process is capable and does indeed produce the intended outputs.

Cross-checking has already been referenced as a recommended activity in audit. However it may not be always possible (indeed it is usually not possible) for an individual auditor to assess whether all the interactions between processes were defined and are adequately and usefully controlled.

Where it is not possible – in very large companies for example - this may/will require involvement of several auditors acting within their individual scope. It is a lead auditor's responsibility to ensure that all these interactions and effectiveness of control thereof is thoroughly assessed, through the input from several auditors.

It will become increasingly important for an audit planning activity to include the need to "sketch" out the Client Company's "process flow"; identifying the described (within the QMS) and expected (from knowledge of the industry involved) inter-relationships in order that the Audit Team have a clear understanding of the ways in which "effectiveness of implementation and conformance" can be checked and evaluated during the Audit.

Auditing Data

The Standard places an increased emphasis on the importance of data within a Quality Management System in order for the Company to be able to:

- Monitor present performance against Quality Objectives.
- Monitor present performance against improvement initiatives.
- Evaluate the effectiveness of the Management System

It is logical to state, therefore, that if data is important to the Company, it is equally important to the auditor. The traditional "auditor virtue" of evaluating evidence is now more relevant and important than ever. It cannot be enough to establish that records exist; the content and "meaning" of those records must be examined and compared with conclusions being reached by the company based on the information and data shown.

It is also going to be even more important than it is now for auditors to crosscheck that the data presented is factual. For example if an auditor is auditing the organization's "Evaluation of Supplier Performance", records the organization's conclusions on particular suppliers should be verified and cross checked against such things as:

- Incoming Inspection records
- Non conforming product records where the non-conformance has been caused by material failures

Auditing Commitment

This has always been a requirement of the Standard and now it is much more clearly expressed as a requirement of a Management approach to Quality Management. It has similarly always been a requirement for auditors to examine and evaluate this management commitment. Always a requirement but always difficult to implement.

The issue remains a fundamentally "dangerous" area – raising a non-conformance "The Management have not provided sufficient commitment ……." is a confrontational statement at any time and not one that the vast majority of auditors would ever "risk" making and certainly this would be an area where the lead auditor would be expected to be directly involved in this part of the audit process.

Although still difficult, the 2000 version does make the task of auditing "Management Commitment, a little simpler than before because there is now clear indication of where Objective Evidence MUST be available for Audit review.

The requirements for Continual Improvement indicate that, in some areas, investment in time and money will be automatically required in order to achieve the desired results. The "follow through" of these requirements and the achievement of the improvements could be seen to be an indicator of the strength of the Management commitment.

Similarly the requirement to evaluate customer satisfaction clearly implies that, in the majority of cases, improvements in this area may well be required. The way in which senior management:

- Identify these needs.
- React to the needs.
- Track the achievement of the improvements required.

This will also provide auditors with the ability to evaluate commitment in real terms by looking at the way in which improvement plans have been implemented and achieved. One area of concern to an auditor must be if there is evidence that previously committed plans have been cancelled SOLELY on the basis of cost as this may well indicate "Lack of Commitment".

What is clear is that interviews with SENIOR Management MUST be part of ANY Audit Plan against the requirements of ISO 9001:2000. The areas that will have to be examined in interview – and there are no real guides on how questions can be asked – will include:

- What do Senior Management mean by "Customer Satisfaction" and "Customer Requirements"? – as these are the foundation of the 2000 Edition and, in one form or another they MUST be included within a Policy Statement. Therefore if the Senior Management does not understand these issues how can the Policy be valid?

- What does Senior Management understand about the overall process and interaction of the "Sub" processes of the QMS and the IMPORTANCE of the Customer requirements being communicated to all levels within the Organization and is this understanding matched by the methods described within the QMS?

An audit and the auditors must focus on the systems collective ability to achieve set objectives NOT simply on the fact that the company have created a documented system who's individual elements address all of the requirements!

Objective evidence should be collected and examined and details recorded on the Checklist. All essential information, for example, identification of the evidence examined, specific details of non-conforming or adverse conditions, together with any applicable references, should be also recorded. If they appear significant, any clues suggesting a non-conformance should be noted and investigated, though the Checklist may not have covered them. Information gained by interviews should be collaborated by acquiring the same information from other independent sources.

In completing the Audit Checklist under the heading **Activity Conformance** the Auditor should state 'Acceptable', 'Not Acceptable', 'Not Applicable' (N/A) or 'See Comment'. The C**omments/Remarks** column should be used to expand on the activity or to reference objective evidence and non-conformances.

When a non-conformance is identified, it is good practice to request the Auditee to acknowledge the finding by appending his/her signature, or initials, to the objective evidence documented in the Checklist. It should be explained that such an acknowledgement does not mean that a request for corrective action will be issued. This will be decided when the results of the Total Audit are subsequently evaluated.

During the Audit, in order to ensure the optimal achievement of Audit objectives, it may become necessary to make changes to the Auditors' work assignments and perhaps to the Audit itinerary or timetable. This is the responsibility of the Team Leader and any such changes should be made in agreement with the Auditee.

Should the Audit/Assessment objectives appear to become unattainable, and then the Team Leader should make the decision to abort the Audit/Assessment and should report the reasons to the Auditee and to his/her own Management.

3. Evaluation of Results - Upon completion of the Audit, and before the Closing Meeting, the Audit Team should meet to consider and evaluate the evidence generated during the Audit. The Team should analyse any apparent non-conformances or adverse conditions to ensure validity as Audit findings. This consideration should also take place where a single Auditor is concerned. Objective evidence of a departure from approved procedures; documented requirements and/or other applicable documents should be considered as valid justification for an Audit finding.

In many instances, non-conformances are categorised and such categorisation relates to the nature of the non-conformance. Categories of non-conformance are listed on page 8.47. It is generally accepted that only Category 1 would be documented as an Audit finding, with Category 2 being treated as an observation.

It is not suggested that categorisation be used in every instance and it is entirely up to the Audit/Assessing Organisation to determine their own procedure in this respect.

Such Audit findings should be recorded and a document known as a Corrective Action Request (CAR) form is a typical vehicle for this.

The Corrective Action Request form should be completed by the Auditor to show only the nature of the non-conformance. The sections for 'Corrective Action', 'Action taken to prevent recurrence' of a non-conformance and 'Follow-up and Close-out' should be left blank at this stage.

Having reviewed the Audit findings and completed any necessary CAR forms, the Auditor (or Audit Team Leader) should convene a meeting with the Auditee to discuss the outcome of the Audit. This meeting, like the entry meeting, is given many titles, such as Closing Meeting, Exit Meeting, Exit Interview, Post-Audit Meeting, and others.

4. The Exit Meeting - At this meeting should be present Top Management, Heads of Departments, the Management Representative(s). The names of all persons attending the meeting should again be recorded in the same manner as for the Entry Meeting.

During this meeting, the Auditor (or Team Leader) should present an overview of the Audit results and should present any findings and ensure that the Auditee understands such findings. At this stage the CARs (if any) should be presented to the Auditee and the Auditee requested to sign the first section of the form to indicate an understanding of the non-conformance. The signature does not indicate an agreement, only an acknowledgement that the finding is understood. A copy of each CAR is left with the Auditee. The Auditor (or Team Leader) should emphasise at this stage that it has not been possible to cover every aspect of the Auditee's Quality System. It does not follow, therefore, that where no non-conformances have been reported none exist.

8.18

The Auditor (or Team Leader) should advise the Auditee of the intended issue date of the Formal Audit Report. Generally this should be within ten working days from the date of the Exit Meeting. It is standard practice to attach the originals of the corrective action requests to the Audit Report and the Auditor (or Team Leader) should make this clear.

The Auditee should be requested to respond to the findings, usually within ten working days of the receipt of the Audit Report. This response entails the Auditee returning the originals of the corrective action requests to the auditing organisation, indicating on the form:

* The corrective action which is to be taken to correct the deficiency, the date by which this will be done and signing it in the appropriate place.

* The corrective action which is to be taken to prevent a recurrence of the deficiency, the date by which this will be done and also signing it in the appropriate place.

It is to be stressed that the response due date is not the date by which the corrective action, and action to prevent recurrence, is expected to be completed but the date by which the corrective action request(s) is (are) to be returned.

Having presented the Audit Results to Senior Management and clarified any ambiguities, the Audit Team should then withdraw.

It is not unusual for an Auditee to request the Auditor to make recommendations to close-out the deficiencies. Internally this could be expected of the Auditor but nevertheless it should be made clear that any recommendations made are purely personal and should not be taken as an instruction.

Externally extreme caution must be taken when making recommendations, as the Auditor may be taken to account if such recommendations are subsequently found to be ineffective.

It is up to the Auditee to determine the extent, the way and the methods for corrective and subsequent preventative actions.

At the Exit Meeting, the Auditee may produce objective evidence, which may nullify a corrective action. Any such evidence should be evaluated to confirm that not only does it correct the deficiency but also prevents a recurrence of the deficiency.

Should it satisfy both counts, and then the CAR should not be withdrawn but closed-out in the normal way and recorded accordingly in the Audit Report.

There may be instances also where the Auditee declines to acknowledge a finding on the CAR, in which case the Team Leader would indicate on the CAR that the Auditee declined to sign. This would be recorded in the Audit Report.

RISKS AND BENEFITS OF A SAMPLING PROCESS

Quality Systems depend on two things: Paper/Electronic Data and People.

During an Audit it is not practical or desirable for an Auditor to look at every document and interview every staff member related to the Quality Systems, there are far too many commercial and practical restraints to make it possible.

The Auditor will therefore “Sample”. This could equally apply to the individuals interviewed, the questions they are asked and the documents they are asked to produce.

By sampling, the Auditor is able to “get a feel” for how any particular procedure is functioning. The Auditor can then either review a larger sample if he feels there is a problem or weakness or if he satisfied with the sample he can move on. By using this technique the Auditor is able to realistically and effectively assess the performance of the Quality Management system.

There are of course risks in using sampling. A problem may exist and yet not be identified if it is outside of the sample taken. An Auditee may if they are aware of a problem be selective when presenting the sample to the Auditor; for this reason the Auditor should always direct the Auditee to the sample they wish to see.

Overall, while it is accepted that sampling is not perfect it is deemed to be a very good compromise and remains an effective tool to the Auditor.

THE AUDIT REPORT

The Audit Report should be prepared by, or under the direction of, the Audit Team Leader who should be responsible for its accuracy and completeness.

The Report should contain the following information, as applicable:

* Organisation audited.
* Scope and objectives of the Audit.
* Details of the Audit itinerary or timetable.
* Identification of the Audit Team members.
* Identification of Auditee's Representatives.
* Identification of the Audit criteria (quality system standard, quality manual, procedures, job instructions, contract work, scope, and others).
* Record of Non-conformances.
* The Result of the Audit.
* Audit Report Distribution List.

Audit Reports, as for any other series of documents, should be presented in a uniform manner and the formulation of such covered by procedure. A typical Audit Report would comprise the following:

* Lead (or Cover) Sheet. (Page 8.53)
* Report Sheet (Page 8.54) Corrective Action Requests.

If so required the completed Checklists could be included as part of the Audit Report. This practice, however, is not recommended as it adds to the amount of paper distributed and could lead to disagreements with the Auditee regarding the objective evidence listed. The completed Checklists should be filed with a copy of the Audit Report.

The results of the Audit should be summarised on the Lead Sheet and any Audit findings (CAR's) should be itemised. By giving a summary on the first page this enables Management to see at a glance the outcome of the Audit. If further information is required, then reference can be made to the details in the body of the Report.

An Audit Summary could read as follows:

Summary of Audit - *The purpose of this Audit was to verify the implementation of document control as covered by procedure No.....(here state document number, title and revision status). The Audit indicated that generally the requirements of the procedures were being implemented but there were certain areas, which would appear to require much closer attention.*

Deficiencies were identified with regard to the delegation of responsibility, the control of document distribution, the review of documentation and maintaining records up to date. These deficiencies have been addressed by a total of six corrective action requests Nos. 001 - 006 inclusive.

The body of the Report should follow a prescribed format and, as an example, should report on:

* The Entry Meeting.
* The Audit itself.
* The Exit Meeting.
* Designated follow-up.
* General observations.

Each heading, if this format is used, should always appear in the Report and when a heading is not applicable the words 'not applicable' should follow beneath the heading. To explain this more fully.

Entry Meeting - Provide a brief summary of the meeting, stating who attended. Avoid too much detail; entry meetings usually follow a very standard pattern. List any specific requests made and/or agreements reached with the Auditee.

Audit - Give a detailed account of the Audit, listing the areas, which were found to be satisfactory, and in conformance with requirements. Detail the areas which were not in conformance with requirements and which it was necessary to address by corrective action requests. Include as 'observations of concern' activities which were deficient but which were not addressed by corrective action requests. If considered appropriate, make constructive ‘recommendations' to the Auditee for rectifying the deficiency but do not be dogmatic (Auditees will usually find another way of correcting a deficiency in any case).

Exit Meeting - Provide a brief summary of the meeting, stating who attended (as for entry meetings, avoid too much detail). Exit Meetings usually follow a standard pattern. Record if any corrective action requests are withdrawn as a result of further discussion and additional information being provided at the Exit Meeting. Record if the Auditee declined to sign a Corrective Action Request (this will also be stated on the Corrective Action Request Form by the Audit Team Leader).

Designated Follow-up - State the intention to undertake a Follow-up Audit to verify closeout of each corrective action request, usually within a defined period of the final date stated for the completion of corrective action and the action to prevent a recurrence of the identified deficiencies.

General Observations - Include any general observations considered applicable and constructive. As an example:

Although generally the requirements of the procedures were being implemented, more attention is required adequately to control document distribution, documentation review and the maintenance of up-to-date records.

If there are no 'general observations' add 'not applicable' beneath this heading.

When complete, the Audit Report should then be signed on the Cover Sheet by the Auditor (or Audit Team Leader) and by the appropriate Supervisor (Corporate Quality Assurance Manager, Chief Engineer, etc.) after he/she has reviewed the Report and the contents have his/her approval.

The original of any Corrective Action Request raised as a result of the Audit should accompany the Audit Report when it is forwarded to the Auditee.

It is considered good practice to ensure that the Audit Report is completed and issued to the Auditee, under a Covering Memo, within fourteen days (ten working days) of the final date of the Audit. The Covering Letter should identify the final date by which responses are required for the Audit findings - Corrective Action Requests.

Report Distribution - It is usual to present the Report to Senior Management of the Auditee. Any additional distribution being determined in consultation with the Auditee at the Exit Meeting.

Audit Reports containing confidential or proprietary information should be suitably safeguarded by the auditing organisation.

Report and Record Retention - Audit documents should be retained in accordance with Agreement reached between the Auditing Organisation and the Auditee. Regulatory requirements should also be taken into consideration when determining record retention periods.

THE FOLLOW-UP

The Auditee is responsible for determining and initiating the corrective action necessary to correct a deficiency and to correct the cause of the deficiency. The Auditor should be responsible only for identifying the deficiency.

Corrective and preventive actions should be completed within a time-scale determined by the Auditee but which is acceptable to the Auditing Organisation. Subsequent follow-up actions should also be similarly undertaken to an agreed time-scale.

Following receipt of the responses to the Audit findings, the Auditor (or Audit Team Leader) should initiate follow-up activities, usually in the form of another Audit, to verify the completion of the action to correct the deficiency and the action taken to prevent recurrence.

If the follow-up indicates that the actions taken have corrected and prevented a recurrence of the deficiency, then the corrective action request can be closed-out. This should be stated on the Corrective Action Request Form in the appropriate section.

If the follow-up indicates that the action taken does not correct the deficiency or does not prevent a recurrence, then this should be stated on the Corrective Action Request Form and the deficiency re-addressed by issuing a revision to the corrective action request.

It may be necessary, in the event of a continuing deficiency, for the Auditor to call in support from Senior Management - hence the requirement of all Quality System Standards that the quality assurance function reports direct to Senior Management.

Audits, Audit Reports, Corrective Action Requests and Follow-up Audits should be controlled and regulated. It is, therefore, prudent to establish and maintain details of all such activities.

Figure 6J is a typical example of an Audit Report Status Log, while Figure 6K shows a typical example of a Corrective Action Request Status Log.

Traceability of documentation is, once again, most important. It will be necessary, therefore, to develop an identification system to control Audit Reports and Corrective Action Requests. Provision is made for this in the respective Status Logs.

A typical identification system for Internal Audits could be a sequence, which links the Audit to the year during which it was carried out. In the following example the first two numbers represent the year followed by the Audit Number:

0101, 0102, 0103 and so on.

For external applications, a Supplier identification, Purchase Order number or Contract number, could be used as a prefix followed by the sequential Audit Number.

Any Corrective Action Requests issued during an Audit should be cross-referenced to the Audit itself to retain traceability. The Audit Number should be used as a prefix followed by the CAR Number, which would commence at 1 (one) for every Audit.

For example, during Audit 0801 three Corrective Action Requests may have been issued and would be identified as follows:

9801-01, 9801-02, 9801-03.

In instances where it is necessary to monitor continually the performance of an External Auditee, surveillance visits would be carried out. Such visits would be undertaken to evaluate the status of procedures, methods, conditions, products, processes and services. An analysis of the records would be undertaken to assure that quality requirements are being met. Generally where the surveillance activity indicates that such requirements are met, then the results of the visit would be documented in a letter confirming this. However, should a non-conformance be identified during such a surveillance visit, then appropriate the Auditee must take corrective action.

THE AUDIT ROUTE

The complete auditing function has been set out on page 8.55 in the form of a Flow Chart, which takes each activity step by step from the formulation of the Quality System through to implementation and adherence. Each activity is identified with the appropriate responsible department and with the interfacing departments and processes.

Following the Chart through from the establishment of the Quality System (a Management responsibility), the procedures and instructions are developed and implemented by the appropriate departments. These procedures and instructions are then audited by the quality assurance function to confirm implementation and effectiveness. If compliant and effective, then the Audit Report is issued to confirm this.

If non-compliant or ineffective then, together with an Audit Report, Corrective Action Requests should be issued on the department concerned. The department should then determine and implement corrective action and the action to prevent recurrence.

If the discrepancy had been a straightforward operator fault, then the action to correct the deficiency would follow the left-hand route on the Flow Chart. The Follow-up Audit would either confirm that the action taken to correct the deficiency and to prevent recurrence was satisfactory, in which case the corrective action request would be closed-out, or the action taken was ineffective, in which case the corrective action request would be reissued.

The discrepancy may be due to a procedural fault. The activity may have been incorrectly documented - the activity itself being perfectly effective (this often occurs when procedures are written by personnel other than those who are familiar with the activity). In such a case, an amendment to the procedure would be required. The revision would then be approved, issued and implemented. A follow-up Audit would be carried out to confirm effectiveness, in which case the corrective action request would be closed-out or, if still non-compliant or ineffective, then the corrective action request would be reissued. Corrective action could go either way, depending on whether the procedure is still ineffective or whether the operator is at fault - thus completing the loop until eventual satisfactory implementation and close-out. In the event of a continuous non-conformance, it will be necessary to refer the problem to senior management for resolution.

THE AUDITOR - GUIDE, PHILOSOPHER AND FRIEND

Throughout the Audit activity, particularly in the early stages of the implementation of Quality Systems, there are bound to be Audit findings. Personnel may well have to get used to doing things differently and the new methods may be foreign to them. The Auditor should not adopt a belligerent attitude but should be the Guide, Philosopher and Friend. To adopt the so-called ‘gotcher’' mentality will lead only to antagonism and non co-operation.

As has been stated, should a deficiency be found and the Auditor asked to make a recommendation regarding corrective action, then by all means assist in this respect but it is prudent to advise the Auditee that the advice given is purely personal and should not be taken as 'gospel'. Wherever possible the Auditee should be left to determine his/her own corrective action.

Experience has shown that recommending corrective action (particularly in the case of external Audits) can create more problems than it solves. The recommended corrective action is invariably taken as an instruction and, when the recommendation is found to be ineffective, the Auditor usually finds the blame laid at his door.

Corrective action, where a major deficiency is concerned, may involve the Auditee in a great deal of time and money. In such instances should the Auditee act upon a recommendation, which is ineffective in its result, and then the Auditee could well be inclined to submit an invoice for the costs involved.

An Auditor should be aware of the implications when recommending corrective action and, therefore, should be very sure of his/her ground. One must have experience with the activity under Audit.

In many instances, particularly where Auditors are inexperienced, the recommendation made when a non-compliant action is discovered is to amend the procedure. Amending the procedure is an easy let-out. A Follow-up Audit by an experienced Auditor usually uncovers the truth. The Auditee hadn't read the procedure in the first place and was, therefore, not aware of the requirement. It is a Management responsibility to make all personnel aware of their commitments.

Once a deficiency has been discovered and reported upon, it is worthwhile keeping in touch with the Auditee to evaluate the progress of corrective action. This acts as a spur to the Auditee and reminds him/her of their responsibilities. It could also highlight any problems, which the Auditee may be experiencing with regard to closeout.

Where an Auditor is acting on behalf of a Flag State, conducting an ISM Audit, it may be necessary to stipulate the precise corrective action and the date by which the corrective action must be accomplished.

ASSESSMENT

As has already been said, an Audit is undertaken to confirm the adequacy and implementation of a Quality System. The basic documentation being the detailed procedures. Audits are Post-Contract activities and, therefore, there is a Contractual requirement to implement a Quality System. Internally, although there is no Contract as such, there is a commitment between Management and workforce to comply with procedural requirements. This could be construed as a Contractual requirement.

There are, however, instances where a Company could be involved in a major purchasing activity and, before tender packages are issued, it will be necessary to establish who is to tender for the item or service. There could be a number of potential Suppliers but, if there were no previous history of a Supplier on record, then it would be prudent to assess that potential Supplier's capability.

The assessment of a Supplier can take many forms. A history of a Supplier's capability can be established purely on a quality/delivery/service record. Where such a Supplier makes frequent and regular deliveries to a Customer, then confidence is established and maintained on a continuing basis. This method of assessment should be documented and updated by delivery analyses.

In other instances, one could verify a Supplier's capability either by inspecting the product at the Supplier's premises before delivery or by incoming inspection on receipt. Although effective, this may not be very economical when the product is rejected. This method of assessment should also be documented and updated by inspection results.

The responsibility for quality should lie with the Supplier and it should not be necessary for the Customer to 'inspect' quality into supplied items.

There are a number of countries - UK, Canada, Australia and others - which operate Assessment Programmes. Assessments are carried out by Accredited Bodies to the appropriate national Quality System Standard and successful Companies are registered accordingly and are entered in a Buyers' Guide. If an Organisation uses such a Buyers' Guide as an assessment source, then this method should be similarly documented.

In the case of very complex plant or equipment, such methods of assessment would not be very meaningful, particularly if additional quality requirements are to be stipulated. It will be necessary, therefore, particularly when the Firm is unknown, to carry out an assessment to verify whether or not the potential Supplier is capable of meeting not only quality requirements but also engineering, service, delivery and economic criteria.

An Assessment, therefore, falls into four distinct parts:

1. Quality.
2. Engineering or service requirements.
3. Economics/schedule.
4. Financial stability.

1. Quality - An evaluation should be made of the potential Supplier's own Quality System. This should be documented in the form of a Quality Manual and an evaluation would verify whether the Quality System is being effectively implemented and receives the full support of Senior Management.

At this stage, with no Contract made, there is nothing binding upon a potential Supplier to conform to any given requirement. It is possible only to review the Quality System and to make observations on any apparent deficiency, perhaps advising the Supplier that the deficiency, if not rectified, could have an adverse affect on Contract award. The Customer's own Quality Assurance Personnel would be responsible for this activity.

2. Engineering or Service Requirements - An evaluation should be made of the potential Supplier's facilities to verify whether they have the capability to manufacture or supply a service to the specification, i.e. goods, services, software, etc.

A study of their fulfilment of recent Contracts of comparable size and complexity should also be undertaken, as this would assist in substantiating the Assessee's capabilities. As this part of the assessment relates to the manufacturing/service capabilities, personnel who are familiar with production/process activities, i.e. qualified personnel should carry it out.

3. Economics/Schedule - An evaluation should be made of the potential Supplier's price and delivery record. Have prices for similar Contracts been competitive and is there a proven ability to deliver on time?

4. Financial stability - An evaluation should be made of the potential Supplier's financial stability, particularly where high-cost, long-delivery Contracts are concerned. In times of recession, it is not uncommon for Companies to go into Receivership. If this should happen, then there is no knowing what effect this could have on Contracts already half-completed (possibly after considerable advance progress payments have been committed - and perhaps lost irrevocably). It is often prudent, therefore, to examine the Supplier's published accounts or seek a report from an Accredited Agency.

The last two items would be evaluated probably by the Customer's Contracts Department.

During the assessment, an evaluation should be made of the Supplier's inspection and test plans for recent orders of comparable size and complexity. This should verify whether the Supplier does take into consideration, during the planning stage, any unique Customer requirements for inspection and testing, and whether mandatory hold-points are documented and adhered to.

All parties involved, resulting in an agreement to approve or disapprove the Supplier, should evaluate the results of the assessment. In the case of approval, the Supplier would then be entered on the Bidders' List.

In summary, therefore, the assessment will always be:

* Pre-Contract.
* Related to a complete Quality System.
* Performed on an organisation outside one's own.

As has been said, the term Audit is not generally used for Pre-Contract Activities.

PLANNING FOR ASSESSMENT

An Assessment differs from an Audit in the early stages prior to the Entry Meeting in the greater degree of specialisation necessary. The Team will include specialists to cover the engineering, production or service requirements and contractual aspects.

These early stages will also differ in the methods of approaching the Organisation to be assessed, the level of pre-assessment and assessment preparation.

The approach to the organisation to be assessed - It is usual for the Purchasing Organisation to forward a questionnaire to the intended Supplier requesting the following:

* Quality documentation, including a Quality Manual.
* Approvals by other Organisations (e.g. National Standards Bodies, Accreditation Bureaux, Major Purchasers, etc.) with the approval standard date of assessment and scope.
* Size and make up of the Organisation, personnel (Q.A. etc.) and location of work.
* Location of premises.
* Floor space.
* Machinery and equipment details.
* Products and services offered.
* Names of key personnel (e.g. Managing Director, Technical Director, Quality Manager).

Level of Assessment - Based on information obtained from the questionnaire, the Assessing Organisation will decide on the appropriate standard to which the Assessment will be performed. Considerable input will be expected at this stage from other disciplines such as engineering, purchasing and others. At this point a Lead Auditor will be nominated and an appropriately sized Team selected. The Team will be made up of specialist functions that will be responsible for assessing their areas of expertise.

Pre-Assessment Preparation - The Assessment Team Leader will evaluate the documents supplied by the Assessee and will advise the Quality Manager on whether the Assessment should proceed.

Assuming an affirmative decision is made, the Assessment Team Leader will then establish:

* The date(s) for the Assessment.
* The Assessment Agenda.
* The Assessment itinerary or timetable.

The Assessee will be requested to supply any further information, which may be required.

It may be desirable for the Assessment Team Leader to make a Pre-Assessment Visit to the Assessee to establish these matters. The Assessment Team Leader would, in effect, "walk the job" and as a result would be able to determine the number of people and the time required to undertake the Assessment. It is very difficult to give a definitive timetable for an Assessment, as it will depend entirely upon the size of the Organisation and the nature of its services and/or products.

MANAGEMENT AUDITS REVEAL

* Interdepartmental responsibilities blurred.

* Procedures tolerated but generally ignored.

* Feedback inadequate (Faults being more easily corrected at the workplace than reported).

* Communications deficient.

THE MAIN QUALITY FAILURES

1. Insufficient planning.

2. Insufficient training.

3. No system for monitoring.

4. Poor documentation control.

5. Lack of Resources.

6. Poor Calibration System.

INTERNAL AUDIT OBJECTIVES

* TO DETERMINE THE IMPLEMENTATION AND EFFECTIVENESS OF ONE'S OWN QUALITY SYSTEM.

* TO DETERMINE THE CONFORMANCE OR NON-CONFORMANCE OF QUALITY SYSTEM ELEMENTS TO SPECIFIED CONTRACTUAL REQUIREMENTS.

* TO PROVIDE A BASIS FOR IMPROVEMENT OF A QUALITY SYSTEM.

* TO MEET REGULATORY REQUIREMENTS.

* TO ACHIEVE SECOND OR THIRD PARTY REGISTRATION.

ASSESSMENT OBJECTIVES

TO EVALUATE A POTENTIAL SUPPLIER WITH A VIEW TO ESTABLISHING A CONTRACTUAL RELATIONSHIP.

EXTERNAL AUDIT OBJECTIVES

TO VERIFY THAT A SUPPLIER'S QUALITY SYSTEM CONTINUES TO MEET SPECIFIED REQUIREMENTS AND IS BEING EFFECTIVELY IMPLEMENTED.

QUALITYAUDIT

Definition:

A systematic, independent and documented Process for obtaining Audit Evidence and evaluating it objectively to determine the extent to which Audit Criteria are fulfilled.

THE ASSESSMENT/AUDIT CONCEPT

During the Assessment or Audit Process the Auditor seeks evidence of:

* Clearly defined responsibility and Authority.

* Documented Procedures, Instructions and Controls.

* Knowledge and understanding of responsibilities, Authority, Procedures, Instructions, etc.

* Processes are identified and established.

* Processes are effective in providing the required results.

* Are interactions between processes defined, controlled and managed.

* Effectiveness of the System when correctly operated.

EXTERNAL AUDIT

AUDITEE RESPONSIBILITIES

* ADVISE EMPLOYEES OF OBJECTIVES AND SCOPE

* APPOINT SUITABLE ESCORTS

* PROVIDE ADEQUATE RESOURCES

* PROVIDE ACCESS TO FACILITIES AND OBJECTIVE EVIDENCE AS REQUIRED

* EMPHASISE CO-OPERATION

* DETERMINE AND IMPLEMENT CORRECTIVE ACTION

Quality Assurance Department Audit Schedule																										
Dept. to be Audited	Year																									
	Month																									
	W/E																									
	Wk.No																									
Purchasing																										
Personnel																										
Training																										
Operations																										
Engineering																										
Chartering																										
Insurance & Claims																										
Safety																										

Audit Schedule Approved:_____

Quality Manager

Date Schedule Approved:_____

Figure 8A – The Audit Schedule

EA-07/01 EA GUIDELINES ON THE APPLICATION OF EN 45012
IAF GUIDANCE ON APPLICATION OF ISO/IEC GUIDE 62

Certificated entity: Number of Employees	Initial assessment (Auditor Days)		Annual surveillance Visits (Auditor Days)		Re-assessment visits (Auditor Days)	
	Total	On-site Min'm	Total	On-site Min'm	Total	On-site Min'm
Less than 5	2	1	1	0.5	1.5	1
5-9	2.5	1.5	1	0.5	1.5	1
10-19	3	2	1	1	2	1
20-29	4	2.5	1.5	1	3	2
30-59	6	4.5	2	1	4	2.5
60-100	7	5	2	1.5	4	3
100-250	8	6	2.5	2	5	3
250-500	10	7	3	2	6	4.5
500-1000	12	9	4	3	8	5.5
1000-2000	15	12	5	4	10	6.5
2000-4000	18	14	6	5	12	8
4000-8000	21	17	7	5	14	9

AUDIT PREPARATION AND PLANNING

* Appoint person(s) to be responsible for the Audit.

* Notify the Auditee.

* Agree Audit Timetable.

* Review relevant documents.

* Brief Audit Team Members.

* Develop Checklists.

ASSESSMENT QUESTIONNAIRE

INFORMATION REQUIRED ON:

1. QUALITY DOCUMENTATION INCLUDING A QUALITY MANUAL.

2. APPROVALS BY OTHER ORGANISATIONS (CERTIFICATION AUTHORITY, STANDARD, DATE).

3. SIZE AND MAKE UP OF ORGANISATION.

4. LOCATION OF PREMISES.

5. FLOOR SPACE.

6. MACHINERY AND EQUIPMENT DETAILS.

7. PRODUCTS AND SERVICES OFFERED.

8. NAMES OF KEY PERSONNEL.

ENTRY MEETING

1. Introductions.

2. Confirm Purpose and Scope of Audit.

3. Review Scope, Timetable and Agenda.

4. Provide Summary of audit Methods and Procedures.

5. Confirm Confidentiality.

6. Clarify any ambiguities of Audit Process.

7. Introduce methods of documenting findings.

8. Agree tentative time for Exit Meeting and invite Senior Management to attend.

9. Arrange for Escorts.

10. Confirm availability of Office and other resources (external only).

11. Arrange for familiarisation tour (if time permits).

ATTENDANCE REGISTER

Company:

Address: **Date:**

Name (Please print)	Position	Entry (initial)	Exit (initial)

AUDIT PERFORMANCE

OBTAIN AND REVIEW OBJECTIVE EVIDENCE

RECORD WHAT YOU HAVE SEEN

IS IT ACCEPTABLE OR UNACCEPTABLE?

WHEN AUDITING

* **USE CHECKLISTS AS A GUIDE.**

* **SEEK AND EXAMINE OBJECTIVE EVIDENCE BY:**

  - **INTERVIEW.**
  - **REVIEW OF DOCUMENTS, FORMS AND RECORDS.**
  - **OBSERVATION OF ACTIVITIES.**

* **FOR EACH PROCESS ON THE CHECKLIST DETERMINE:**

  - **WHAT THE ACTIVITY SHOULD PRODUCE.**
  - **IS IT PRODUCED?**
  - **IS IT AVAILABLE?**
  - **IS IT COMPLETE?**
  - **HOW DOES IT INTERRELATE WITH OTHER PROCESSES?**

* **RECORD SPECIFIC DETAILS OF THE OBJECTIVE EVIDENCE THAT HAS BEEN EXAMINED ON THE CHECKLIST.**

* **DETERMINE WHETHER THE ACTIVITY COMPLIES WITH THE REQUIREMENTS OF:**

  - **COMPANY POLICY AS EXPRESSED IN PROCEDURES AND INSTRUCTIONS.**
  - **THE RELEVANT QUALITY SYSTEM STANDARD.**

* **RECORD THE ACTIVITY CONFORMANCE ON THE CHECKLIST.**

EXIT MEETING

1. **Introductions (if personnel different from Entry Meeting).**

2. **Overview of Audit Results.**

3. **Audit is a Sample.**

4. **Confidentiality**

5. **Presentation of any findings.**

6. **Advise intended Issue Date of Audit Report.**

7. **Confirm date of response by Auditee to any Audit Findings.**

LEAD AUDITORS RESPONSIBILITIES

- Assist with the selection of Team Members.
- Prepare the Audit/Assessment Itinerary.
- Notify the Auditee/Assessee.
- Control all activities within the Audit/Assessment Process.
- Responsible for the conduct of Audit/Assessment Team Members.
- Determine categories of non-conformances.
- Submit Audit/Assessment Report.
- Direct follow-up actions as and when required.

CATEGORIES OF NON-CONFORMANCE

MAJOR

1. AN ELEMENT OF THE STANDARD NOT ADDRESSED.

2. AN ACTIVITY THAT IS IN DIRECT CONTRAVENTION OF THE STANDARD.

3. AN ACTIVITY WHICH IS IN DIRECT CONTRAVENTION OF A PROCEDURE AND WILL HAVE A CONSEQUENTIAL EFFECT ON THE QUALITY OF THE PRODUCT OR THE SERVICE.

MINOR

AN ISOLATED INCIDENT OF A NON-CONFORMANCE WITH A SYSTEM OR PROCEDURAL REQUIREMENT, WHICH HAS NO DIRECT CONSEQUENTIAL EFFECT ON THE QUALITY OF THE PRODUCT OR SERVICE.

TRENDS OF MINOR NON-CONFORMANCES COULD LEAD TO A MAJOR NON-CONFORMANCE IF A SIGNIFICANT NUMBER OF INCIDENTS OF THE SAME DEFICIENCY ARE ENCOUNTERED.

OBSERVATION

COMMENTS ON THE QUALITY SYSTEM WITH A VIEW TO IMPROVEMENT.

MAJOR: ALSO CALLED "CATEGORY 1" OR “UNACCEPTABLE".
MINOR: ALSO CALLED "CATEGORY 2" OR "CONDITIONAL".
OBSERVATION: ALSO CALLED “CATEGORY 3”.

COMPANY NAME:	QUALITY MANAGEMENT SYSTEMS	CAR NO:
	CORRECTIVE ACTION REQUEST	DATE: AUDIT NO:

Company/Department Audited and Address:

Auditor:	Company/Department Representative:	Clause:

NON-CONFORMANCE:

Signed* .....…….. Signed .....
Company/Department Representative Auditor
*Signature indicates understanding

CORRECTIVE ACTION

Signed .....…… Date:
Company/Department Representative

ACTION TAKEN TO PREVENT RECURRENCE

Date action to prevent recurrence to be completed:

Signed .....……... Date:
Company/Department Representative

FOLLOW-UP AND CLOSE OUT

Proposal Follow-up Date:

Follow-up Details

Date CAR Closed Out: Signed .....
Auditor

The Corrective Action Request

AUDIT FOLLOW-UP

AN AUDIT FOLLOW-UP ENTAILS**:**

- VERIFYING THE IMPLEMENTATION AND EFFECTIVENESS OF SPECIFIED CORRECTIVE ACTION IN CORRECTING A PREVIOUS AUDIT FINDING.

- VERIFYING THE EFFECTIVENESS OF SPECIFIED CORRECTIVE ACTION IN PREVENTING A RECURRENCE OF AN AUDIT FINDING.

- CLOSING OUT AN AUDIT FINDING WHEN SPECIFIED CORRECTIVE ACTIONS VERIFIED AS EFFECTIVE.

- ADDRESSING AS AN AUDIT FINDING A SPECIFIED CORRECTIVE ACTION WHICH HAS BEEN FOUND NOT TO HAVE BEEN IMPLEMENTED OR NOT TO HAVE BEEN EFFECTIVE.

AUDIT FOLLOW-UP
RESPONSIBILITY FOR CORRECTIVE ACTION

AUDITOR	AUDITEE
IDENTIFY AND DESCRIBE THE NEED FOR CORRECTIVE ACTION	
	ACKNOWLEDGE THAT THE NEED HAS BEEN IDENTIFIED
AGREE UPON THE TIMING FOR THE COMPLETION OF CORRECTIVE ACTION AND THE ACTION TO PREVENT A RECURRENCE.	
	DECIDE AND CARRY OUT CORRECTIVE ACTION
	ESTABLISH THAT CORRECTIVE ACTION IS EFFECTIVE AND DESCRIBE THE ACTION ON THE CAR FORM
VERIFY THAT THE CORRECTIVE ACTION AND THE ACTION TO PREVENT RECURRENCE HAVE BEEN EFFECTIVE	
CLOSE OUT THE CAR	

AUDITOR VIRTUES

AN AUDITOR SHOULD ALWAYS:

*	PREPARE:	Know the subject Material.
*	LEARN:	**T**horoughly about Auditee.
*	CONTROL:	The Audit.
*	ASSIST:	Where there is misunderstanding.
*	LISTEN:	To what the Auditee is saying.
*	OBSERVE:	Good business ethics.
*	OBTAIN:	Objective evidence.
*	COMPLIMENT:	The Auditee.
*	BE CONCISE :	Keep questions short and to the point.

AUDITOR SINS

AN AUDITOR SHOULD NEVER:

* Compare the Auditee with others.
* Be sarcastic.
* Swear.
* Criticise.
* Be side tracked.
* Argue.
* Discuss personalities.
* Discuss religion or politics.
* Discuss Company Policy.
* Drink before an interview.
* Be late.

COMPANY NAME:	QUALITY MANAGEMENT SYSTEMS	AUDIT REPORT NO:
	AUDIT REPORT	Page 1 of

CONTRACT:

CONTRACT NO:

AUDITED ORGANISATION:

PURCHASE ORDER NO:

ADDRESS:

AUDIT CRITERIA:

DATE OF AUDIT:

DATE PREVIOUS AUDIT:

TEL. NO:

PREVIOUS AUDIT NO:

PERSONS CONTACTED:

AUDIT TEAM:

SUMMARY OF AUDIT:

SIGNED .....
(TEAM LEADER)

SIGNED .....
(QUALITY MANAGER)

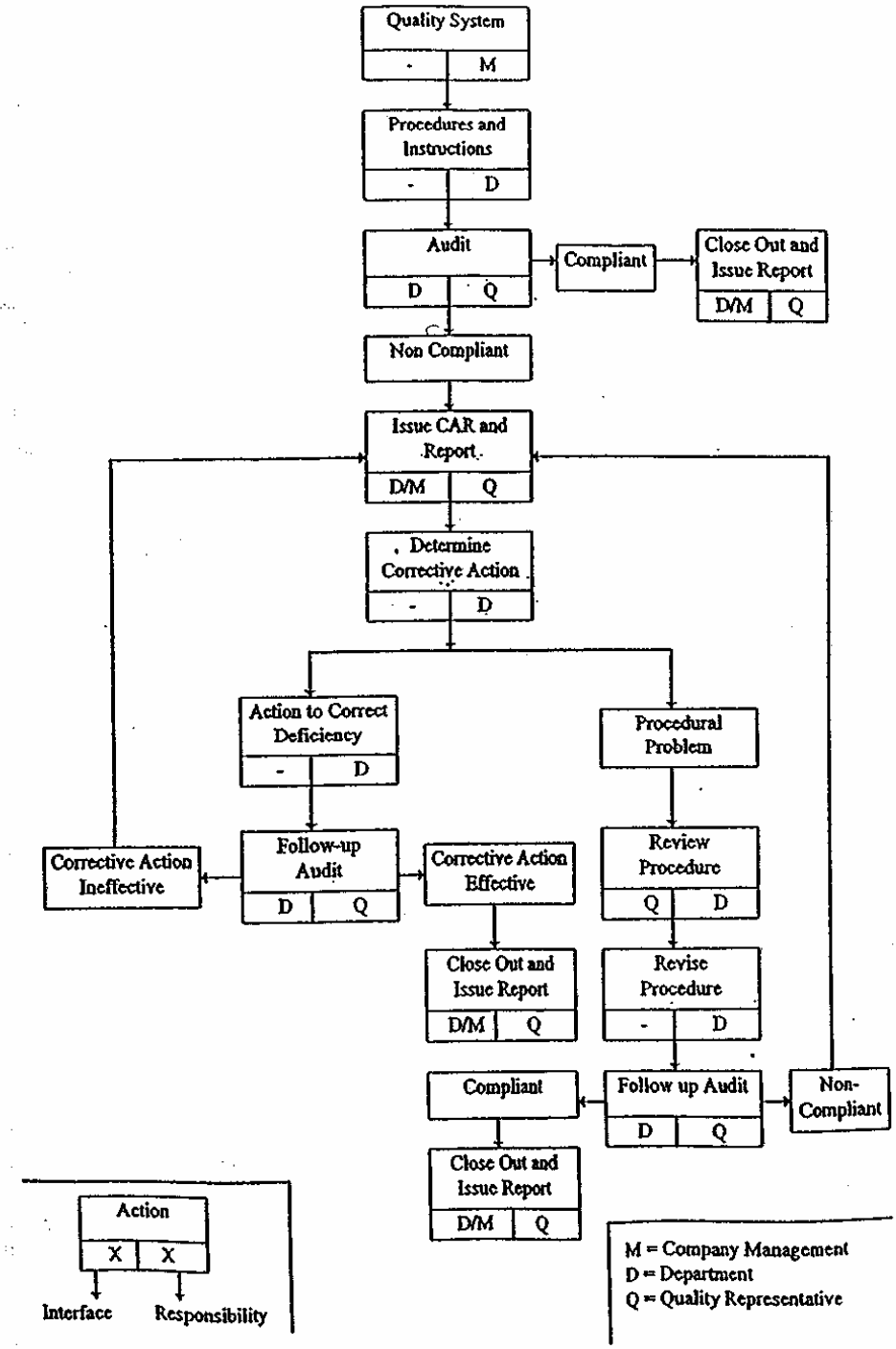
DATE:

DATE:

The Audit Report (Lead Sheet)

COMPANY NAME:	QUALITY MANAGEMENT SYSTEMS	AUDIT REPORT NO:
	AUDIT REPORT	Page 2 of

The Audit Report


Quality System
- M
Procedures and Instructions
- D
Audit
D Q
Compliant
Close Out and Issue Report
D/M Q
Non Compliant
Issue CAR and Report
D/M Q
Determine Corrective Action
- D
Action to Correct Deficiency
- D
Procedural Problem
Corrective Action Ineffective
Follow-up Audit
D Q
Corrective Action Effective
Review Procedure
Q D
Close Out and Issue Report
D/M Q
Revise Procedure
- D
Compliant
Follow up Audit
D Q
Non-Compliant
Close Out and Issue Report
D/M Q
Action
X X
Interface
Responsibility
M = Company Management
D = Department
Q = Quality Representative

PART 9

HUMAN FACTORS

IN THE

AUDIT PROCESS

Human Interaction	**9.1**
The Attributes & Personality of the Auditor	**9.1**
The Attributes & Personality of the Auditee	**9.4**
Knowledge Base of the Auditor	**9.5**
Ramifications of the Audit Process	**9.5**
Advice for the Auditor	**9.6**
Conclusion	**9.8**

FACTORS IN THE AUDIT PROCESS

HUMAN INTERACTION

Various types of Audits have been discussed. External - the Auditor, therefore, may be called upon to perform either an Internal Audit or External Audit (for simplicity's sake the term "Audit" will be used throughout) and these will exert different pressures on the Auditor. The External Audit requires a greater degree of formality, planning and control but gives the Auditor slightly more opportunity to distance him/herself from the Auditee in the human interaction relationship, whereas the Internal Audit requires a greater degree of sensitivity on the part of the Auditor as it involves interaction with colleagues.

In Internal Audits, the Auditee may be a relation (it could even be one's spouse!), friend, future boss, future employee or Supervisor. In other words, there are a number of potential "chasms" in the human relations area that may reduce the effectiveness of the Audit and/or damage the harmony of the working environment. It is, therefore, important that one is able to recognise difficulties in the human interactions area, either in oneself or in one's fellow Auditors.

One must, therefore, always be aware of the purpose of the Audit that is to verify, by the examination and evaluation of objective evidence that an Organisation's quality activities are in conformance with the documented Quality Management System. If quality activities are not in conformance, then the reason for the non-conformance must be determined and investigated. The Auditee, in turn, should evaluate the results of the Audit and determine where improvements to the System can be made.

Potential problems in the interaction with the Auditee can be divided into four broad areas, namely:

1. The Attributes and Personality of the Auditor.
2. The Attributes and Personality of the Auditee.
3. The Knowledge Base of the Auditor.
4. The Ramifications of the Audit Process.

THE ATTRIBUTES AND PERSONALITY OF THE AUDITOR

Fail the Auditee!

The purpose of the Audit is to determine conformance or otherwise in an objective manner, not to find a non-conformance at all costs. There exists a common misconception that an Auditor has not performed an adequate job unless he/she has found a non-conformance and the more non-conformance's found, the more effective the Audit. This is certainly not the case! If the Auditee's System complies, then complete the Audit and document the results. One will have performed a useful function.

Should a non-conformance be observed, then the Auditee must be advised, in an objective manner, of the details of the non-conformance, together with the reasons why it is believed that the non-conformance exists. Making a "song and dance" about it, or telling others, may only embarrass the Auditee. This will lead to antagonism and non co-operation in the future. Training and counselling the Auditor may overcome the problem.

An over simplification would be to compare the role of the Auditor with that of a Doctor. In both cases each must maintain the confidentiality of the Auditee (Patient) and have the integrity not to embarrass or antagonise the Auditee (Patient).

The Autocratic Auditor

There are some people who instinctively see the Audit Process as their right to give commands to change procedures and instructions that do not form part of their day-to-day responsibilities. This happens particularly in the case of Internal Audits.

Being an Auditor does not give one the right to be the "new General Manager". If one is giving commands, one cannot effectively listen.

Disregarding the Auditee's response could lead to antagonism and non co-operation.

Counselling and training of the "over zealous" Auditor may rectify the problem.

The "Wish to be Friends"

At the opposite end of the scale is the Auditor who wishes to be friends with everyone and sees auditing as a threat to that relationship. As a result, difficult questions are avoided and the Auditor becomes easily distracted, with the Audit subsequently becoming ineffective.

If the feeling is that auditing may threaten one's future relations with the Auditee then there are a number of options that can be considered such as:

* Further training of the Auditor in how to be objective.
* Training of the Auditee in the purpose of an Audit and how it is undertaken.
* Utilising two Auditors to perform the Audit.
* Using two or three Auditors on a rotation system.
* Stressing that it is the S*ystem* being audited and not the individual.

One is then able to distance oneself from the consequences of the Audit by addressing non-conformances as S*ystem* problems not individual problems. Bearing this in mind, therefore, it is quite possible to undertake an objective Audit (particularly during an internal activity) on a friend or colleague. In other words "never point the finger at an individual - relate the problem to the System'. More often than not, most difficulties experienced when auditing a friend or colleague occur only during the first few audits or until both parties are aware of the Audit Process and its objectives.

Furthermore, as has previously been stressed, any advice or recommendations should be given with extreme care. If advice or recommendations are made, and subsequently found by the Auditee to be ineffective, then this could result in a credibility problem.

The Untrusting Auditor

Beware the Auditor who believes that every Auditee is out to hide something or intends to dupe the Auditor. This attitude will result in suspicion and mistrust between the two parties. An Auditor cannot listen effectively to an Auditee's response if he/she disbelieves everything the Auditee is saying or is looking for a hidden meaning.

Training and counselling may rectify the problem or, alternatively, replacing the Auditor if it is practical to do so.

The Friendly Icebreaker

A competent Auditor has the ability to put the Auditee at ease via the opening comments and subsequent questions. The Auditor should at all times encourage a spirit of openness and friendliness in order to progress the Audit.

The danger is that, unless the Auditor has been well trained, opening comments said in jest (as an Ice-breaker) may have the opposite results. The Auditor should be careful that comments (or comments made to lighten difficult situations) should not be demeaning, slanderous, discriminating or frivolous.

It is very difficult to recover the situation after saying something foolish and then following with a statement such as "I'm an Auditor - take me seriously".

Auditing skills come with practise, observation of other Auditors and observation of the body language of the Auditee. At the end of an Internal Audit, it is prudent to subject oneself to a critical self-assessment and evaluate which parts of the Audit worked for you or against you. This will create a foundation for improvement in one's own audit styles and techniques.

The Tired Auditor

Auditing like any other job function becomes tedious with repetition. One must, therefore, be aware of the Auditor who "has had enough" as his/her audits will become ineffective. This Auditor will lose interest and tenacity in the Audit Process. The problem is that lethargy is like a computer virus; it spreads easily to others and is difficult to detect and remove.

It is recommended that one seeks opportunities to rotate the permanent Auditor with other quality tasks or involve the Auditor in other quality related projects.

In the internal situation particularly, the converse situation is also a potential problem, i.e. the Auditor who has other responsibilities. In this situation the Audit may be postponed due to "other commitments". The only message this gives the Auditee is that the Audit Process is not important.

Again, whenever possible spread the load over a number of Auditors and set a target for the maximum number of postponed audits in a month, or quarter, etc. (depending on frequency).

ATTRIBUTES AND PERSONALITY OF THE AUDITEE

The Aggressive Auditee

A number of people, particularly Managers, have great difficulty in accepting another person asking questions about their particular work activities. The Audit, in this instance, is looked upon as a threat to their position and the Auditor is viewed as a Policeman or a Senior Management/Client Spy.

There are four possible resolutions in a situation such as this:

1. Undertake awareness/training sessions highlighting the objectives and benefits of the Quality Audit Process.
2. Counselling by Senior Management.
3. Win over the sceptics with suitable charisma and charm and avoid becoming defensive, antagonistic, easily distracted, shy or quiet with the resultant inability to carry out an effective Audit.
4. Some reactions may be defensiveness due to lack of understanding of Quality Management System documentation. If this is the case, explain the intent of the document and postpone the Audit, advising Senior Management of the reasons why.

There is also the possibility that the Auditee is strongly negative to the whole concept of the Quality Management System. This may be as a result of lack of training or understanding in the benefits, approach and objectives. Further training and counselling of the Auditee should be considered. One approach is to plan the first few audits to be "quick and simple" and thus ease the Auditee into his/her role.

The "Disorganised" Auditee

Quite often one finds the following situations arise:

* The Auditee is not available at the appointed time, having left his/her Office without leaving a message or having gone to a meeting.
* The Auditee makes some comment such as "it's not today is it?"
* Constant telephone or employee interruptions making it difficult to control the continuity of the Audit.

Unfortunately, it is the people who present such situations who then complain about the Audit taking too long. The answer to this is relatively simple - stop the Audit and suggest that it be postponed to a more opportune time.

Further action, such as issuing instructions regarding holding or transferring telephone calls, curtailing interruptions, and so on, may also be necessary. Continuing difficulties such as these should be advised to Management, through the Audit Team Leader, for action.

KNOWLEDGE BASE OF THE AUDITOR

For an Audit to be effective the Auditor must have a good knowledge of the Quality System Standard being used and the relative procedures, this is essential for the new 2000 version of the Standard.

To cover the requirements of the ISM Code the Auditor must have a full knowledge and understanding of the ISM Code as published by IMO. In certain cases the same individual may have both skills and in this case he will be able to conduct a combined ISO and ISM Audit.

Without this knowledge, the Auditor may:

* Place the incorrect level of importance on an aspect of the standard or procedure.
* Ask questions well outside the scope of the Audit or responsibilities of the Auditee.
* Ask questions that would have the Auditee doubt the competence of the Auditor.

With Internal Audits of a large Organisation, it is quite common for the Auditor to be viewed as the "Technical Expert" and not trained in auditing skills. In this case, there is also the danger that the Audit will degenerate into a technical discussion rather than a Systems or Conformance Audit.

It is, therefore, of the utmost important that the Internal Auditor should be trained in the Audit Process.

It is also advisable for the Auditor to have some knowledge of current Industry Practices, Contractual Requirements and Regulatory Requirements.

If the Auditor is insufficiently trained, he/she may be easily deceived or side tracked by the Auditee.

RAMIFICATIONS OF THE AUDIT PROCESS

Recommendations

As has already been said, the Auditor should be wary of giving recommendations for corrective action. Auditing, to a certain extent, is a matter of opinion. What one Auditor may class as acceptable, another may deem to be non-compliant.

Should the Auditee seek a means of correcting the non-conformance then give an opinion only and stress that it is only an opinion. It is, therefore, inadvisable to create a situation where a recommendation is given and subsequently found to be ineffective. The Auditee will undoubtedly place the blame at the Auditor's door and the Auditor's credibility will be lacking from that day on.

Audit Report

It is most important for the Auditee to receive prompt feedback on the results of the Audit. This should be in the form of a Verbal Presentation at the Exit Meeting followed by a documented Audit Report. If the Auditor pays scant attention to communicating the results of the Audit, the Auditee will care little about maintaining his/her own System.

The "Loose" Audit by Upper Management

Upper Management should be aware of the ramifications of the Loose or Unstructured "walk around' Audit. While this has positive benefits in terms of Staff/Management relations and communication, the negative aspect is the undue importance placed on minor non-conformances.

There is, occasionally, a lack of balance between the positive and negative aspects sighted. If the Loose Audit uncovers a possible non-conformance, it should be followed up with a formal Unscheduled Audit.

ADVICE FOR THE AUDITOR

It should always be remembered that auditing is a complex relationship between the Auditor, the Auditee and the situation. The Auditor should, therefore, be aware of the way he/she should react to a given situation and of the image he/she should convey to the Auditee. The Auditor will come under the scrutiny of the Auditee so, in effect, will be judged on results.

The Auditor should therefore:

* Learn as much as possible about the Auditee.
* Know the subject material.
* Maintain control of the Audit.
* Cultivate a proper attitude.
* Observe good business ethics.
* Recognise that one's position may be considered an imposition.
* Be seen to be competent.
* Keep questions short and to the point.
* Be a good listener.

As far as the last item is concerned, there is an art to being a good listener, which can be summed up as follows:

* **Stop talking!**
  You cannot listen if you are talking.
  Polonius (Hamlet): "Give every man thine ear, but few thy voice".

* **Put the talker at ease.**
  Help a person feel free to talk.
  This is often called a relaxed environment.

* **Show a talker that you want to listen.**
  Look and act as if you are interested. Do not read while someone talks.

* **Remove distractions.**
  Don't doodle, tap or shuffle papers.
  Will it be quieter with the door shut or the telephone disconnected?

* **Empathise with the talker.**
  Try to see the other person's point of view.

* **Be patient.**
  Allow plenty of time. Do not interrupt a talker. Don't start for the door or walk away.

* **Hold your temper.**
  An angry person creates a block to useful discussion.

* **Go easy on arguments and criticism.**
  This puts people on the defensive and they may 'clam up' or become angry. Do not argue: even if you win, you lose.

* **Ask questions.**
  This encourages a talker and shows that you are listening and are interested.

* **Stop talking.**
  This is first and last, because everything else depends on it. You cannot do an effective listening job while you are talking.

Nature gave people two ears but only one tongue, which could be construed as a gentle hint that one should listen more than talk!

Auditors who do not listen have less information for making sound decisions, but these decisions must be made also upon the evaluation of objective evidence.

The primary tools of the Auditor are therefore:

* Questioning.
* Listening.
* Observing (objective evidence).

On the other side of the coin, however, there are certain things an Auditor should not do, such as:

* Don't be late for the meeting; being late puts one on the defensive.
* Don't be sarcastic.
* Don't discuss personalities.
* Don't argue.
* Don't criticise.
* Don't be negative.
* Don't question beyond the level of your knowledge.
* Don't compare the Auditee with others.
* Don't be secretive.
* Don't permit disagreement between team members during a meeting.
* Don't use profane language.
* Don't get involved in emotive discussions.

There is still much unknown about the psychology of performing an Audit just as there is much unknown about human behaviour in general. The Audit Scene is a combination of personalities and climates. It integrates the Auditor, the Auditee and the situation.

Many aspects of human behaviour, that directly affect the Auditor, cannot be easily changed. However, if the Auditor is aware of those attributes, that affect one's ability to perform, one can minimise their affect on the outcome of the Audit.

CONCLUSION

There is no single answer to the control of human factors in the Audit Process. However, merely by recognising a difficulty as it occurs and taking the necessary corrective action will assist greatly. The important aspect is to enter into an Audit as well prepared as possible. Auditors must have, therefore, a good understanding of Quality System Standards, Standard Requirements and Auditing Techniques before an Audit is undertaken. Difficulties will always be encountered if the Auditee knows little about the Quality System. Hence, training of all employees in the benefits of the Quality Management System is important.

9.9

In summary therefore the Auditor should be:

* Articulate.
* Assured.
* Communicative.
* Competent.
* Diplomatic.
* Flexible.
* Honest.
* Judicious.
* Observant.
* Patient.
* Punctual
* Thick-skinned.
* Unbiased.
* Unruffled.

or the Guide, Philosopher and Friend mentioned earlier.

PART 10

AUDITOR/LEAD AUDITOR

QUALIFICATION AND TRAINING

Qualification and Training	**10.1**
Certification Criteria	**10.3**
Fees for Certification	**10.6**
Certification Criteria	**10.10**
Code of Conduct	**10.13**
Acceptable Audits	**10.13**
List of IRCA Documents	**10.15**

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AUDITOR/LEAD AUDITOR QUALIFICATION AND TRAINING

The Auditor has set out to examine the adequacy of the system for assuring quality and as for a financial audit; one would expect the Quality System Auditor to be qualified, experienced and independent.

QUALIFICATION AND TRAINING

A Quality Audit is not as simple as it may appear. The Auditor must have the right attributes. Apart from the appropriate background, there are other necessary requirements and in the main, these fall into three distinct categories:

1. Education.
2. Training.
3. Experience.

1. Education - The requirement here is that auditor candidates should have completed secondary education and should be able to demonstrate competence in reading and writing. Candidates also should be capable of clearly and fluently expressing concepts and ideas orally and in writing in their national language.

2. Training - Auditor candidates should have undergone training to the extent necessary to ensure their competence in the skills required for carrying out audits and for managing audits.

Training in the following areas is regarded as particularly relevant:

* Knowledge and understanding of Quality System Standards.
* Auditing techniques of examining, questioning, evaluating and reporting.
* The skills required for managing an audit, such as planning, organising, communicating and directing.
* Knowledge and understanding of the ISM Code.

Such competence should be demonstrated by written or oral examination or other means acceptable to the Auditing Organisation.

3. Experience – For ISO 9000:2000 Auditor candidates should have the appropriate practical experience with a minimum of two years in quality assurance activities.

Industrial experience includes such fields as Science, Technology, Engineering, Manufacturing, Construction, Services, Administration, Health Care, Economics, etc.

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For ISM, Auditor candidates must have practical experience of shipboard activities and an ideal Auditor could well be a person who has been in command or a Chief Engineer.

In the UK a scheme for the certification of auditors of Quality Systems has been developed, which is controlled by an independent governing board and administered by the Institute of Quality Assurance (IQA). The scheme is recognised by the Department of Trade and Industry and is independent of any sectional interests.

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This Certification Scheme operates for the qualification and certification of Provisional Auditors, Auditors, Lead Auditors and Principal Auditors engaged in the auditing of Quality Systems against criteria contained in national or international Standards. They may be acting either for Purchasing Organisations conducting Second Party Audits or Independent Certification Bodies and similar Organisations conducting Third Party Audits.

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In 1994 this Scheme became international and is now known as the International Register of Certificated Auditors (IRCA) and a number of international certification bodies have agreed to participate in this scheme on a reciprocal basis.

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The requirements of the Scheme could be used to establish criteria for internal auditing capability. Internal Auditors are now certified as part of the main scheme. An information pack may be obtained from the Secretariat on request (see details below). The application pack is free of charge:

Deleted: capability,. although IRCA has a separate Registration Scheme for Internal

Deleted: .

The International Register of Certificated Auditors (IRCA)
P. O. Box 25120
12, Grosvenor Crescent
London SW1X 7ZL
England

Telephone: +44 (0) 20 7245 6833
Facsimile: +44 (0) 20 7245 6755
E-mail: irca@irca.org
Web Site: www.irca.org

IRCA also are able to give the same Classification for Maritime Auditors and information will be supplied on request.

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CERTIFICATION CRITERIA

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The criteria for Certification with IRCA is based on the following five Elements:

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A. Academic qualifications.
B. General work experience.
C. Safety/Quality work experience.
D. Formal auditor training.
E. Auditing experience.

Applicants for Certification must have satisfactorily complied with Elements A, B, C and D to be eligible for any Grade of Certification. An exception may apply to Element A where the educational qualifications fall short of the stated criteria by where all other criteria are satisfied. In such instances IRCA may require additional criteria (see 5 below).

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Deleted: or require an interview to assess the suitability on the basis of overall competence.¶
¶

Satisfying Elements A, B, C and D only will qualify the applicant for the Grade of Provisional Auditor. Further auditing experience as detailed below will qualify the applicant for Auditor, Lead Auditor or Principal Auditor Grades.

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A. Academic Qualifications

The applicant must have successfully completed at least secondary education.

Deleted: an academic programme of education. For certification purposes an acceptable programme of education must meet all the following: -¶
¶
<#>The applicant was at least 18 years of age at the start of the programme¶
<#>The duration of the programme was at least 600 hours of study¶
<#>There is documentary evidence of satisfactory completion of the programme and not simply of attendance¶
<#>The level of achievement at the end of the programme is such that the student who successfully completes it is considered a person of professional competence.¶

Certificates of competence required by airline pilots, navigators, merchant navy officers etc are acceptable if issued by a national governmental body.

The IRCA maintains and is able to refer to an extensive database of recognised technical, academic and professional qualifications awarded in most countries throughout the world.

B. General Work Experience

Applicants must have at least 5 years full-time general work experience, 4 years with degree or near degree.

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Periods of training will not be considered as eligible towards this criterion.

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C. Quality Work Experience

Applicants must have completed at least 2 years full-time work experience (1 year for Internal Auditors) within a context where quality issues formed the major part of the job. Such experience must have provided the applicant with the practical knowledge necessary to audit effectively, quality management systems.

D. Formal Auditor Training

All applicants shall have successfully completed;
either
an IRCA certificated Auditor/Lead Auditor course or acceptable alternative;
or
IRCA certificated courses that cover ISO 9000 foundation and Internal Auditing or acceptable alternatives. This training option is valid only for certification to Internal Auditor grade;
or
a QMS Auditor Training Course certified to the International Auditor and Training Certification Association (IATCA) course approval criteria presented by a Training Organisation approved either by IRCA or by one of the other signatories of the IATCA Multilateral Recognition Agreement for training course approval.

Successful completion of formal auditor training must have occurred within the three-year period immediately prior to application for certification.

For certification as a Maritime Auditor the individual must also in addition to the above have completed and passed an ISM Auditing course or a combined approved ISO/ISM Lead Auditor Course.

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5. Auditing Experience

An applicant who satisfies Elements A, B, C and D but who has insufficient, or no acceptable auditing experience, may be registered to the Provisional Auditor Grade.

For Auditor Grade
To be registered to the Auditor Grade, an applicant must have completed a minimum of 4 acceptable audits. This must be at least a total of 20 days, 10 of which can be document reviews. The totality of auditing experience must involve document review, audit activities and audit reporting.

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All experience submitted in support of an application under this heading must be verifiable and must not total less than 20 days duration, at least 10 of which must have been acquired on-site.

For Lead Auditor

To be certified to the Lead Auditor grade, an applicant must have completed in addition to the requirements for certification to the Auditor grade, a further 3 acceptable audits as leader of an audit team which included at least one other auditor, totalling 15 days, minimum 10 days on site. These audits must have been completed under the direction and guidance of an auditor competent as a team leader.

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For Principal Auditor

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Principal Auditor grade is the most recent addition, and is for experienced auditors who operate on their own. It is designed as an alternative to Lead Auditor grade. This grade recognises the experience and competence of two categories of auditors:

1. Consultancy background – competence in implementing management systems and performing all aspects of the audit process.
2. Lead auditor background – competence in audit management and team leadership.

An applicant must complete a minimum of 7 acceptable sole or lead audits totalling 35 days, 20 days of which must have been acquired on site. All audits submitted in support of certification, irrespective of grade must have been completed within the 3-year period immediately prior to application.

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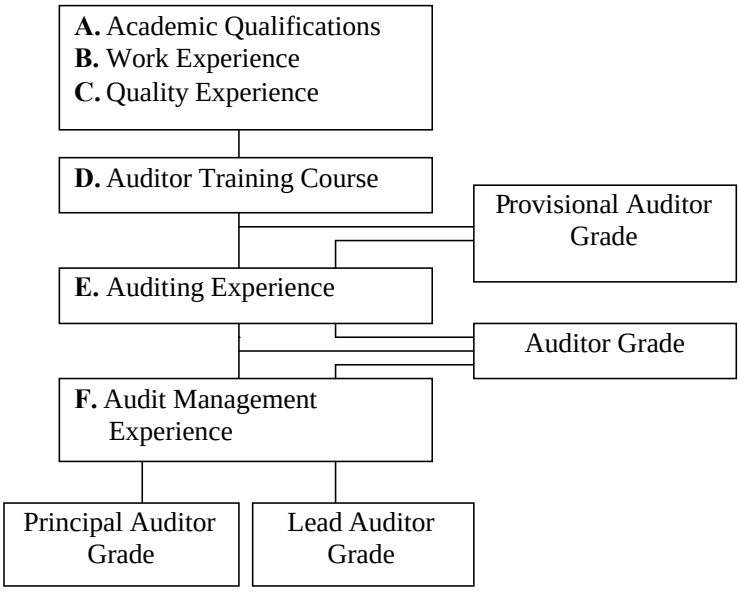

Not all types of audit are considered acceptable for certification purposes. Please refer to Supporting Information (f) on page 10.9 More information is available at www.irca.org

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Processing the application usually takes around six (6) weeks. However, the processing time depends significantly on the time required to verify the information submitted with the application. IRCA consider verification as an essential element supporting the overall credibility of the certification process. Consequently, great care is taken by the IRCA Reviewing Officers in reviewing and verifying applications against all aspects of the certification criteria. However, unusual educational qualifications, former (or current) employers slow to respond to IRCA enquiries, and Auditees that are not helpful, will inevitably delay the processing.

FEES

Fees are determined annually and apply for the calendar year (1st January - 31st December). Current fees are detailed on the Fee Schedule; IRCA/153.

a) **Application Fee**

Must accompany the completed Application Form. This covers the administration involved in processing the application. This fee will not be refunded if the applicant is not successful.

b) **Initial Certification Fee**

This fee covers the cost of the administration of your certification during the first year. This fee must be paid before certification is awarded.

c) **Annual Certification fee**

Due on receipt of a Fee Notice dispatched in October each year. The following year's Certification Card will not be issued until this fee is received.

d) **Sector Scheme Fees**

Auditors registered in a Sector Scheme are charged an additional fee to reflect the extra administration involved.

Fees involved in initial certification will be the application fee plus the annual certification fee (plus sector scheme fee if appropriate). The annual certification fee for the first year may vary according to the month in which certification was awarded.

e) **Application for Regrade Fee**

This fee covers the administration required for each regrade consideration. This fee is due with the regrade submission and is not refundable. Where a regrade application is successful no further fee is required for certification to the new grade for that current year.

Applications for regrading will be considered at any stage during the Auditor's certification period. Regrading offered as a result of evidence provided in support of the re-certification process will not attract an additional fee.

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SUPPORTING INFORMATION

a) Certification as a 'Sector Scheme' Auditor

Certification requirements for all Sector Schemes such as "Maritime Safety Management Systems" are detailed separately. Copies of these requirements may be obtained from the Secretariat on request.

b) The Certification 'Year'

The certification year is a calendar year, i.e. January 1st to December 31st. Certification cards are issued for all current registrants during January. Cards issued to new registrants will be valid for the year of issue only, (including January for the year following) even if this period is only part of the year.

This is not to be confused with the 'Certification Period' as explained below.

c) The Certification 'Period'

The certification period is the three-year period during which registrants are required to have performed five acceptable audits.

The years are calendar years, commencing on the first January following initial certification, or the January following regrading.

During the certification period, at the end of the first and second year, certification may be maintained by payment of the annual certification fee and compliance with the IRCA Code of Conduct. No additional submissions are required to maintain certification. At the end of the third year, all registrants are required to complete the re-certification process.

Re-certification requirements are detailed below.

d) Re-certification

All Auditors are required to re-register every three years, i.e. at the commencement of the next year following three completed years.

For re-certification to Internal Auditor grade, the Auditor must have performed at least five audits totalling 15 hours.

For re-certification to Auditor grade, the Auditor must have performed at least five audits.

For re-certification to Lead Auditor grade, the Auditor must have performed at least five acceptable systems audits, any two of which must have been as the Audit Team Leader.

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For re-certification to Principal Auditor grade, the Auditor must have performed at least five acceptable systems audits either as lead or sole audits.

All audits must have been completed within the previous 3 year certification period.

In addition all auditors (except Internal auditors) must have completed 45 hours of acceptable continuous personal development over the previous three year period.

For all grades, Auditor must not have incurred any complaints during this period which, if substantiated are deemed to have breached the IRCA Code of Conduct.

In the latter part of the third year the Secretariat will write to inform the Auditor of the requirements to re-register at the beginning of the following year and will provide details of the process and the information required.

e) **Standards other than ISO 9001:2000**

Some Quality System Standards are considered equivalent to or are an acceptable alternative to ISO 9001:2000. Audits against these other Standards may be acceptable for certification purposes.

IRCA maintains a register of equivalent or acceptable alternative Standards. This register is not exhaustive and it is possible that applicants may claim audits against a Standard not familiar to IRCA. IRCA have a procedure for considering new Standards and applicants are advised to contact the Secretariat where they may suspect a standard falls within this category.

f) **Certification Cards, Certificates and the Register**

A ***Certification Card*** will be issued following the award of certification and annually following payment of the certification fee and meeting the other stated criteria. This card is the primary evidence of currency or certification and should be presented on commencement of an audit and thereafter on demand as appropriate.

The ***IRCA Certification Certificate*** is intended for display as a formal indication of certification to a specific grade. It should not be used as proof of certification. Certificates may be purchased from the Secretariat. IRCA do not publish a ***Register*** per se, rather a bespoke register is generated for each order according to specific instructions. Due to the numbers of registrants and the rate at which this is increasing, publication and distribution of an annual register incorporating all registrants is not considered practicable or cost effective.

Registers are available on request from IRCA. A charge will apply according to the size and complexity of the register ordered.

g) **Appeals, Complaints and Disciplinary Proceedings**

Registrants have the right to appeal against any decision taken by IRCA. IRCA operate a Quality System that includes established procedures for considering appeals.

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Similarly, complaints made by registrants against IRCA, by registrants against a fellow registrant or by Auditee or other body against a registered Auditor will be considered according to established procedures.

IRCA retain the right to undertake disciplinary procedures against registrants who are found to be in breach of the IRCA Code of Conduct. Options available include suspension of certification and in instances of serious or sustained breach, withdrawal of certification.

Notices of withdrawal of certification are always published within the public domain.

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h) **Confidentiality**

All information, correspondence and documentation submitted by applicants for certification, or by existing registrants, in support of certification activities will be considered as strictly confidential. However, IRCA reserves the right to publish relevant details of each registrant in the Register, except where the registrant expressly forbids publication of these details.

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In addition, the name and country of residence of each new registrant is published in the IQA publication, ***Quality World.***

i) **Legal Status**

The Certification of Auditors by IRCA and all activities associated with the administration of the Register is governed in accordance with English Law and is subject to the exclusive jurisdiction of the English Courts.

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Appendices

Appendix 1. Code of Conduct.

Appendix 2. Types of Audits Acceptable for Certification Purposes.

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Appendix 3. List of IRCA Documents.

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Certification Criteria for Maritime Auditors

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Introduction

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This scheme has been developed for the purposes of registering Auditors trained in the principles and practices of auditing within the Marine Industry sector. The scheme is based on the International Management Code for the Safe Operation of Ships and for Pollution Prevention (abbreviated to International Safety Management Code (ISM Code) and certification is performed by IRCA in conjunction with The Nautical Institute.

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Certification Criteria

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All applicants are required to consider the sector scheme certification criteria stated in this document in conjunction with the core scheme criteria detailed in **IRCA/602/02/2**; *Certification as a Quality Management Systems 2000 (QMS 2000) Auditor*.

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Applicants for Maritime Safety Management Sector Scheme certification are ***not*** required to have existing certification as IRCA registered Quality Management Systems Auditors. However, any successful applicant registered as a Maritime Safety Management Systems Auditor will only be eligible to operate as an Auditor within this sector (and not as a general quality systems Auditor, or within any other sector environment).

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1. **Academic Qualifications**

Core Scheme requirements apply, except that there is ***no*** provision for alternative route by interview where the requirements are not fully met.

In addition applicants are expected to hold at least one of the following:

a) Degree in Nautical Science, Marine Engineering or Naval Architect.
b) Under STCW 95, Deck Officer II/2 or Engineer Officer III/2 or recognised equivalent.

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2. **Work Experience**

A minimum of 4 years experience is required in one or more the following activities:

a) Full-time experience in Master, Chief Engineer, First Mate, Second Engineer, Superintendent or Manager, engaged in organising, managing and operating ships, surveying ships or providing specific marine consultancy.
b) Related experience in Quality Assurance, Marine Safety or Environmental Management.
c) Experience in auditing to the Marine Safety Management (ISM) Code.
d) Principal or Senior Lecturer in a Maritime College teaching courses that lead to the qualifications stated in A.

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If a member of an Institute, state membership grade and number.

Experience as a cargo surveyor, ship builder, ship designer, or ship repairer is ***not*** acceptable.

3. **Quality Experience**

No specific quality experience required, except as stated in **B** above.

4. **Auditor Training**

Core Scheme requirements apply. In addition, applicants must have successfully completed the ***Auditing Maritime Safety Management Systems*** training module. As an alternative, and where this is offered, applicants may take a variant of the core Auditor/Lead Auditor course that is specifically designed for auditors in the Maritime environment.

For certification purposes training course certificates are only valid for 3 years from date of course.

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5. **Auditing Experience**

The following requirements apply:

Auditor (Maritime)

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Requires a minimum of 5 audits, consisting of a maximum 4 against the ISM Code for the issue of the Ships Safety Management Certificate and a maximum of 2 audits for the purpose of issuing the Document of Compliance for the Shipping Company (all shall have been completed within the 3 year period prior to application). Applicants shall state on their audit logs which certificate has been issued for each audit.

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Lead Auditor (Maritime)

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Requires a minimum of a further 5 audits (in addition to those specified above) as team leader, leading a team of 2 or more Auditors. The overall total of 10 audits shall include 1 audit (as team leader) for issuing the Document of Compliance to a Company managing a minimum of 10 vessels, or include 2 audits (as team leader) for issuing the Document of Compliance for Companies managing less than 10 vessels.

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Provisional Auditor (Maritime)

Applicants who meet the requirements of the 1 to 4 above, but cannot satisfy 5. Audit Experience, may be offered the grade of Provisional Auditor (Maritime).

(Provisional Auditors may apply for upgrade at any time, but must meet the relevant criteria specified at the time of application).

1st, 2nd, 3rd Party audits carried out in accordance with IRCA/602/02/2 Appendix 2 will be accepted for certification provided they are performed against a management system that includes all the elements of the ISM Code. ISO9001:2000 audits are ***not*** acceptable.

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6. **Re-certification**

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The Core Scheme requirements for re-certification apply, although all qualifying audits shall have been performed against a management system that includes all the elements of the ISM Code.

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From 1st January 1998 all Auditors shall maintain currency of knowledge of developments relevant to this scheme, by completing at least 45 hours of Continual Professional Development (CPD) spread equally over the 3 year re-certification period. Successful completion of an IRCA Certificated *Updating Auditor Skills* course would fulfil part of the CPD requirements. Further details on CPD may be obtained from the IRCA Secretariat.

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Appendices

Appendix 1. Code of Conduct.

Appendix 2. Types of Auditors Acceptable for Certification Purposes.

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Appendix 3. List of IRCA Documents.

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Appendix 1 IRCA Code of Conduct

It is a condition of certification that registrants rigorously observe the following IRCA Code of Conduct.

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1. To act in a strictly trustworthy and unbiased manner in relation to both the Organisation to which they are employed, contracted or otherwise formally engaged (the Audit Organisation) and any other Organisation involved in an audit performed by them or by personnel under their direct control.

2. To disclose to their employer any relationship they may have with the Organisation to be audited before undertaking any audit function in respect of that Organisation.

3. Not to accept any inducement, gift, commission, discount or any other profit from the Organisations audited, from their Representatives, or from any other interested person nor knowingly allow personnel for whom they are responsible to do so.

4. Not to disclose the findings, or any part of them, of the Audit Team for which they are responsible or of which they are part, or any other information gained in the course of the audit to any third party, unless authorised in writing by both the Auditee and the audit Organisations to do so.

5. Not to act in any way prejudicial to the reputation or interest of the Audit Organisation.

6. Not to act in any way prejudicial to the reputation, or interests or credibility of IRCA.

7. In the event of any alleged breach of this Code, to co-operate fully in any formal enquiry procedure.

Appendix 2 Types of Audits Acceptable for Certification Purposes

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First Party Audits

First Party (Internal) Audits will be accepted only where there is complete independence of the Organisation's audit function from its operational activities and where the audits are full systems audits conducted in accordance with ISO 19011:2002. In many respects this type of first party audit will resemble a third party audit.

Second Party Audits

Second Party Audits performed in accordance with ISO 19011:2002, will be accepted where it may be demonstrated that the scope of the audit included all elements of the Standard and was planned and performed in a similar manner to third party audit.

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Third Party Audits

Third Party Audits performed in accordance with ISO 19011:2002.

Audits against Standards (other than ISO 9001:2000)

Audits carried out against alternate, National or Company Standards may be acceptable. Applicants are advised to contact the Secretariat for advice and/or to submit a copy of the Standard to IRCA for evaluation with the application.

Consultancy Audits

A contractually specified audit carried out by a Consultant against criteria of an IRCA recognised Quality Systems Standards on behalf of a Client, will be acceptable providing:

* The Client prior to the audit was operating a fully documented and established Quality System.

* The Consultant had no part in setting up the Quality System that is subsequently the subject of the audit.

* The Consultant is totally independent of the Client Organisation.

* The Consultant has no involvement in the ongoing development of the System.

* A full System Audit was carried out.

In the event where a Consultant has been involved in the development and implementation of the Quality Systems prior to Certification by a Certification Body, the pre-assessment audit may exceptionally be acceptable for certification providing:

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* The Client Company obtained certification at the first attempt;

and

* There was no major non-compliance's requiring corrective actions as a condition of the awarding of certification.

Types of Audit NOT Acceptable for Certification

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* Surveillance Audits are not accepted for application for initial certification. For the purpose of re-certification five surveillance audits will be considered equivalent to one full systems audit.

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* Audits of a particular Quality System, which are repeated more frequently than once a year.

* Audits of less than one day's (six hours exclusive of breaks) duration.

* Close out and follow up visits.

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Appendix 3 List of IRCA Documents

Certification as a Quality Management Systems 2000 Auditor	IRCA/602- latest issue.
Application Form for Certification	IRCA/103- latest issue.
Audit and Training Log	IRCA/106- latest issue.
Audit and Training Log - Specimen	IRCA/106- latest issue.
Supplementary Maritime (ISM) Audit Log	IRCA/150- latest issue.
IRCA Auditor Certification Fees 2002	IRCA/153- latest issue.
Application for Transfer	IRCA/631- latest issue.

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Various other documents and booklets are available, see the website at www.irca.org for full details.

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PART 11

DELEGATES NOTES

COURSE HANDOUTS

AND

COURSE ACTIVITIES