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DEVELOPMENT INFORMATION CENTER

RD1E

IISE Awareness Training on Quality and ISO 9000

Technical Report No. 99/5

September 1999

Submitted by:

Chemonics International, Inc.

Under Contract No. 492-C-00-98-00029-00
Associated Number 492-0444
United States Agency for International Development

November, 1999

Ms. Priscilla P. Rubio
Cognizant Technical Officer
Office of Environmental Management
U.S. Agency for International Development
Ramon Magsaysay Building
1680 Roxas Boulevard, Malate, 1004
Manila, Philippines

Subject: IISE Awareness Training on Quality and ISO 9000

Project: Industrial Initiatives for a Sustainable Environment (IISE)
Contract No. 492-C-00-98-00029-00

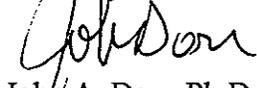
Dear Ms. Rubio:

In accordance with the requirements of the subject contract, we are pleased to submit a report on the IISE Awareness Training on Quality and IQO 9000 conducted by the project's Quality and Environmental Management Systems Program Coordinator, Ms. Jacqueline Limtin which was held in Cebu on September 23-24.

This seminar was held as part of IISE's overall training program designed to facilitate the promotion of the projects objectives.

If you have any questions regarding this report, please do not hesitate to contact me.

Sincerely,



John A. Dorr, Ph.D.
Chief of Party

Enclosures

cc: see report distribution list

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Coastal Resource Management Project

Forest Resource Management Project

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ECODIT

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Pollution Control Association of the Philippines

Welcome to
IISE Awareness Training on
QUALITY & ISO 9000
Sept. 23-24, 1999

Quality & ISO 9000 Training Course Description:

1st part: Introduction - Quality & ISO9000

Introduces the ISO 9000 Quality Assurance standards, and describes the typical ISO9000 process.

2nd part: ISO9000 Implementation

Recommends several steps to be taken for ISO 9000 series standards implementation and certification/registration. Steps on how to select a consultant to meet your needs will also be recommended.

Objectives:

To gain an understanding of the concept of quality, and how ISO 9000 can be used to give assurance to customers that quality is maintained.

To acquire information on how to implement ISO 9000 and achieve certification/registration

Quality & ISO 9000

Some of the benefits that companies which use the ISO9000 standards report are as follows:

- ✓ Better use of time and resources
- ✓ Increased efficiency
- ✓ Less duplication of work
- ✓ Fewer errors
- ✓ Less waste
- ✓ Cost saving
- ✓ Improved profits

Quality & ISO 9000

PERCEPTION



Quality & ISO 9000

Definition of **QUALITY**

the ability to meet all the needs & expectations of the buyer of goods or services

(taking into account the TIME/COST Factors)

In practical terms, **QUALITY** is:

Conformance to requirements

Fitness for purpose

Meeting customer expectations

Exceeding customer expectations

Superiority to competitors

Quality & ISO 9000

Quality Control

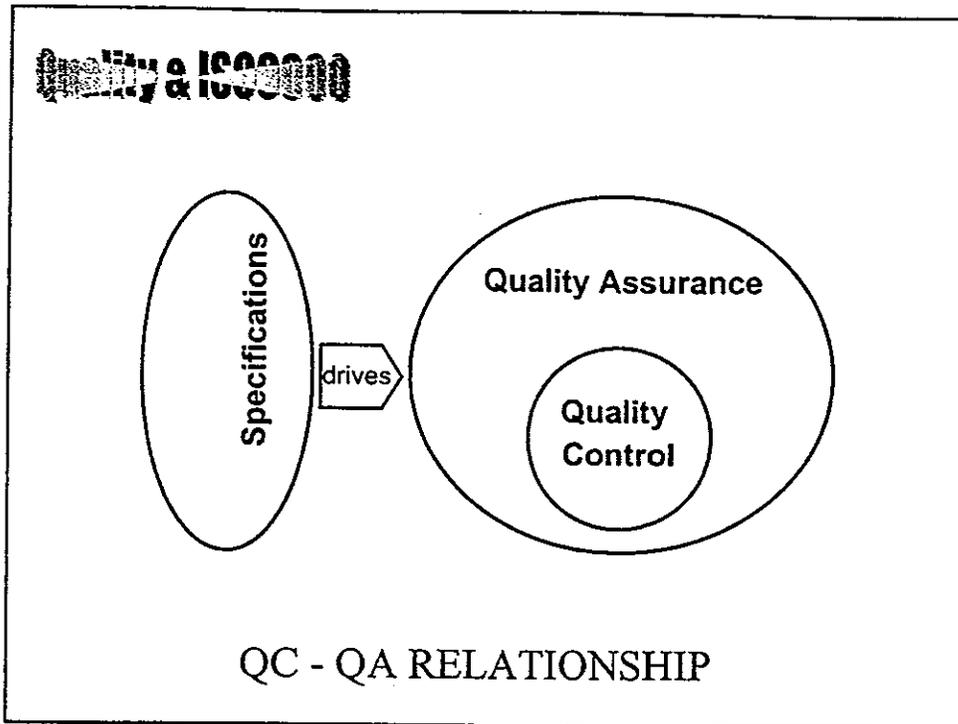
"The operational techniques and activities that are used to fulfill the requirements for quality."

Sort GOOD from BAD parts

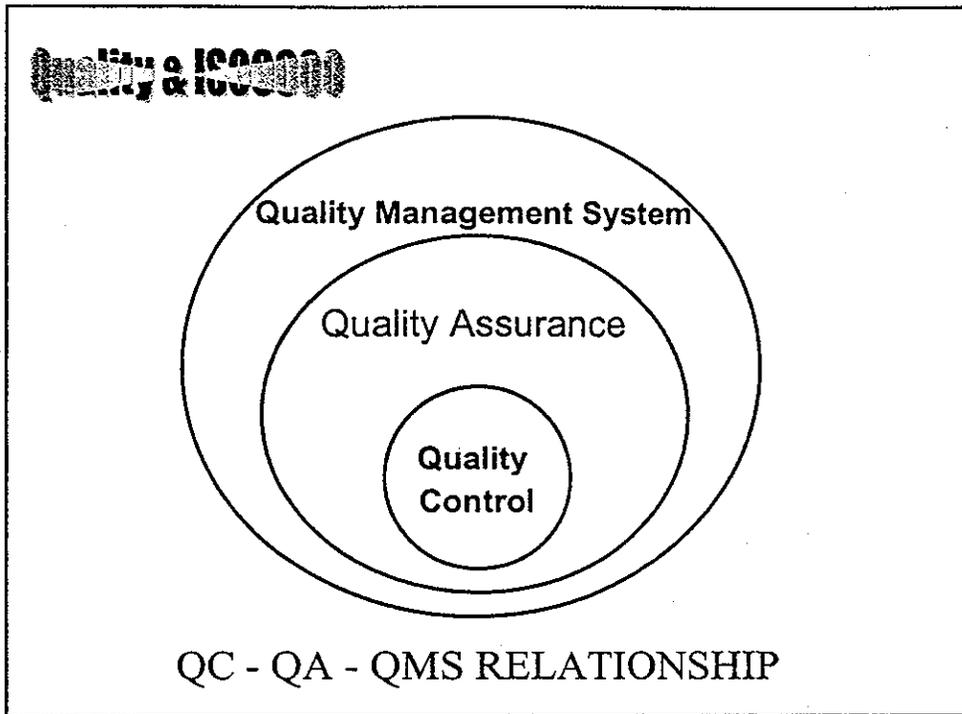
Quality Assurance

"All the planned and systematic activities necessary to provide adequate confidence that a product or a service will fulfill requirements for quality."

Any planned action to prevent Quality problems from occurring



- Quality & ISO 9000**
- Typical QC actions / QA activities:
- | | |
|--|--|
| <ul style="list-style-type: none">> In-process inspection of component dimensions> Non-destructive testing> Final non-destructive testing | <ul style="list-style-type: none">> The production and use of vendor rating systems> The carrying out of audits> The development of a training log> The appointment and training of quality personnel |
|--|--|



Quality & ISO 9000

Quality Management System
System to establish quality policy and quality objectives and to achieve those objectives.

*This includes
the organizational structure, responsibilities,
procedures, processes and resources
for implementing quality management."*

Philosophy of **PREVENTION** rather than
DETECTION

Quality & ISO 9000

PRODUCT LIABILITY

HEALTH AND SAFETY

Quality & ISO 9000

ISO stands for
International Organization for Standardization

The objective is to PROMOTE TRADE

2 kinds of standards:

- * PRODUCT STANDARDS
- * SYSTEM STANDARDS

Quality & ISO 9000

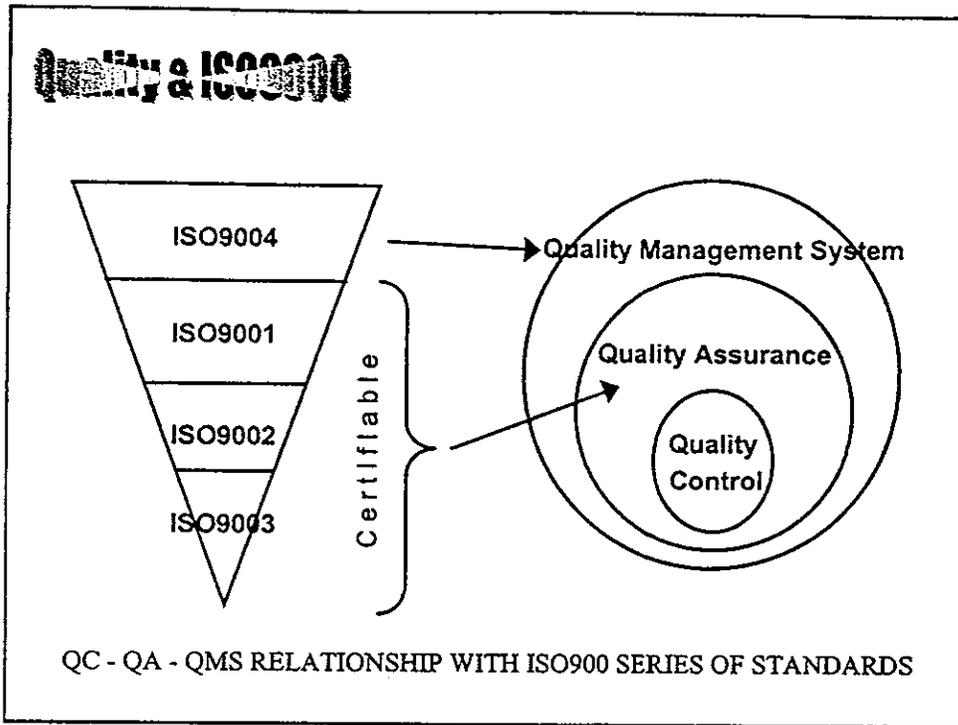
Some Quality System standards issued by ISO:

<u>Name of standard</u>	<u>Applies to:</u>
ISO 9004: Quality Management Management System Guidance	Guidance for performance improvement
ISO 9001/2/3: Quality Systems Model for quality assurance	General supplier qualification

Quality & ISO 9000

The ISO 9000 series of QA standards

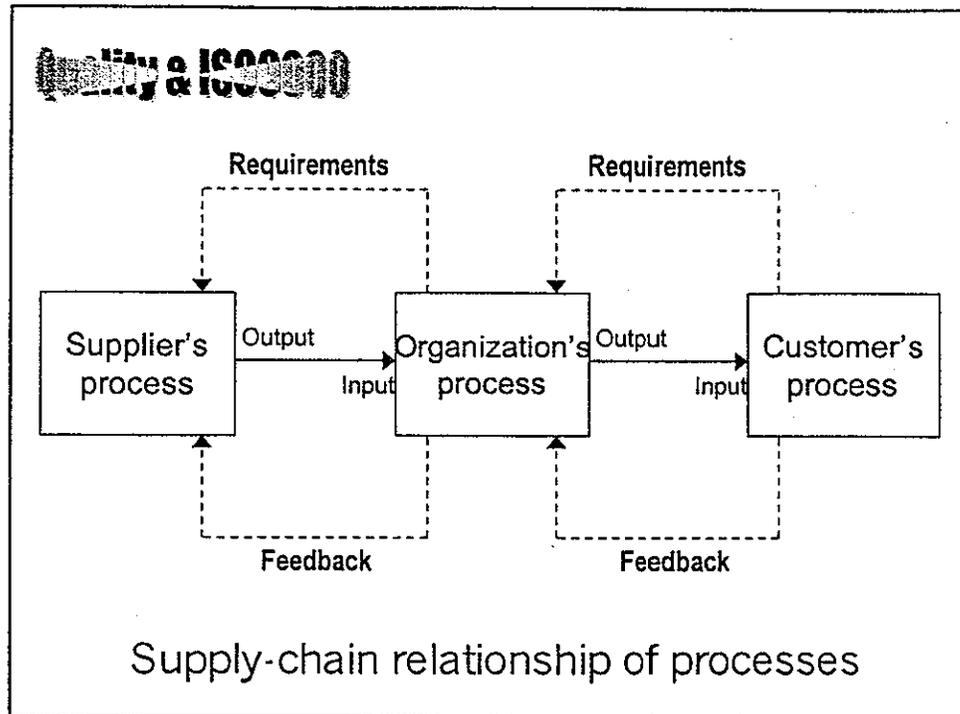
- ISO 9004 covers everything + QMS.
- ISO 9001 covers the areas of design and development, production, installations and servicing of products or services.
- ISO 9002 is limited to quality management in production and installation.
- ISO 9003 covers quality assurance obligations of the supplier in the areas of final inspection and testing.



Quality & ISO9000

ISO 9001 / 9002 Clause Titles

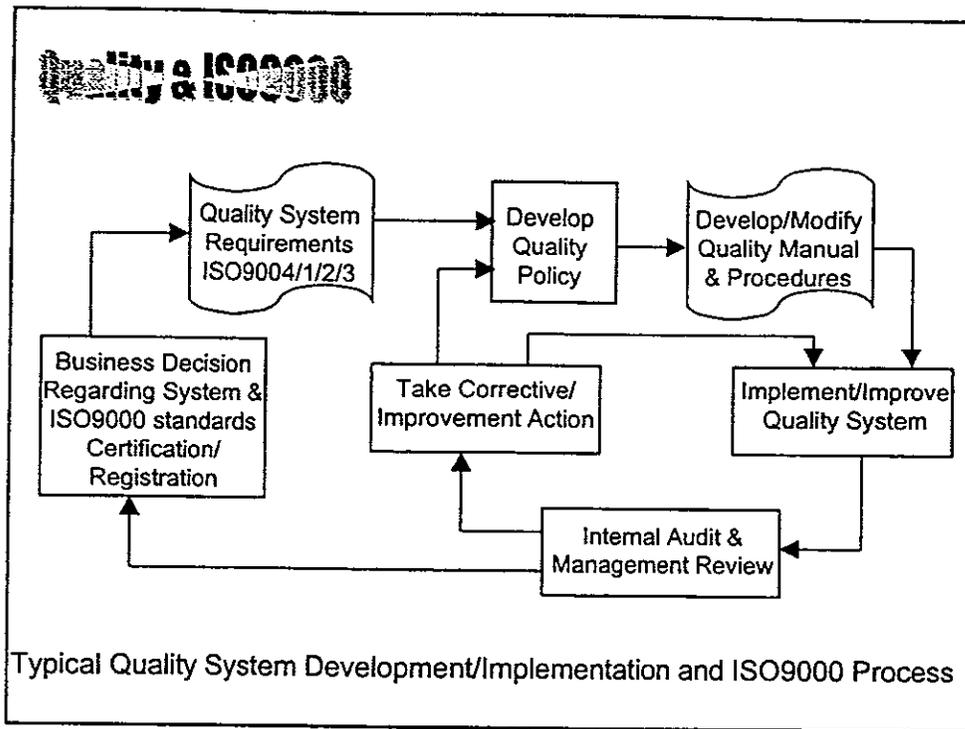
4.1 Management Responsibility	4.12 Inspection & Test Status
4.2 Quality System	4.13 Control of Nonconforming Product
4.3 Contract Review	4.14 Corrective & Preventive Action
4.4 Design Control - N/A for ISO9002	4.15 Handling, Storage, Packaging, Preservation & Delivery
4.5 Document and Data Control	4.16 Control of Quality Records
4.6 Purchasing	4.17 Internal Quality Audit
4.7 Customer Supplied Product	4.18 Training
4.8 Product Identification & Traceability	4.19 Servicing
4.9 Process Control	4.20 Statistical Techniques
4.10 Inspection & Testing	
4.11 Inspection, Measuring & Test Equipment	



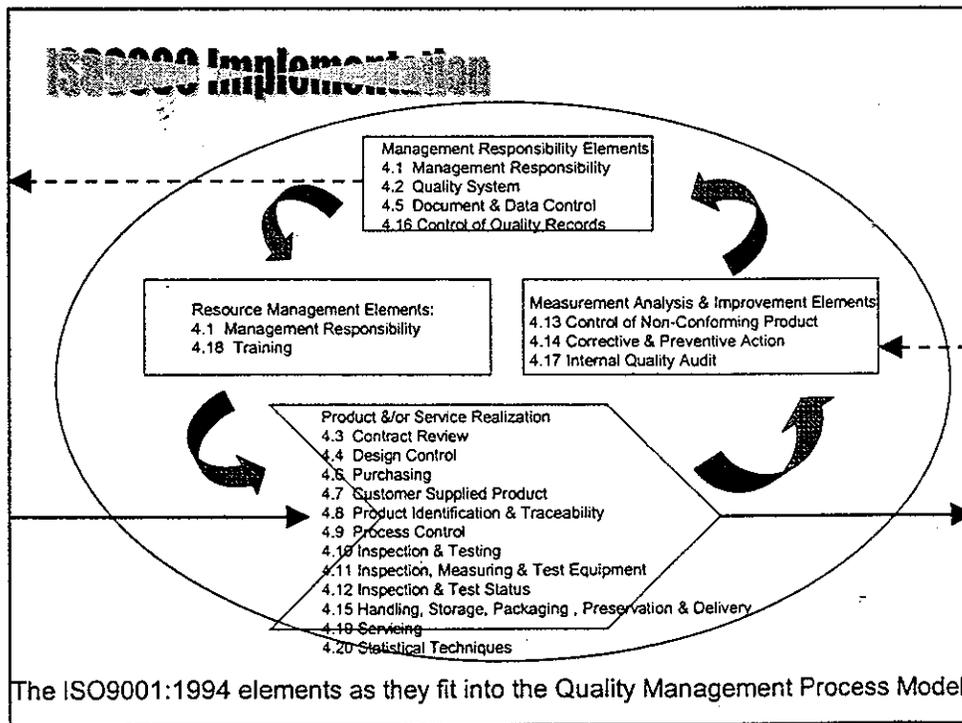
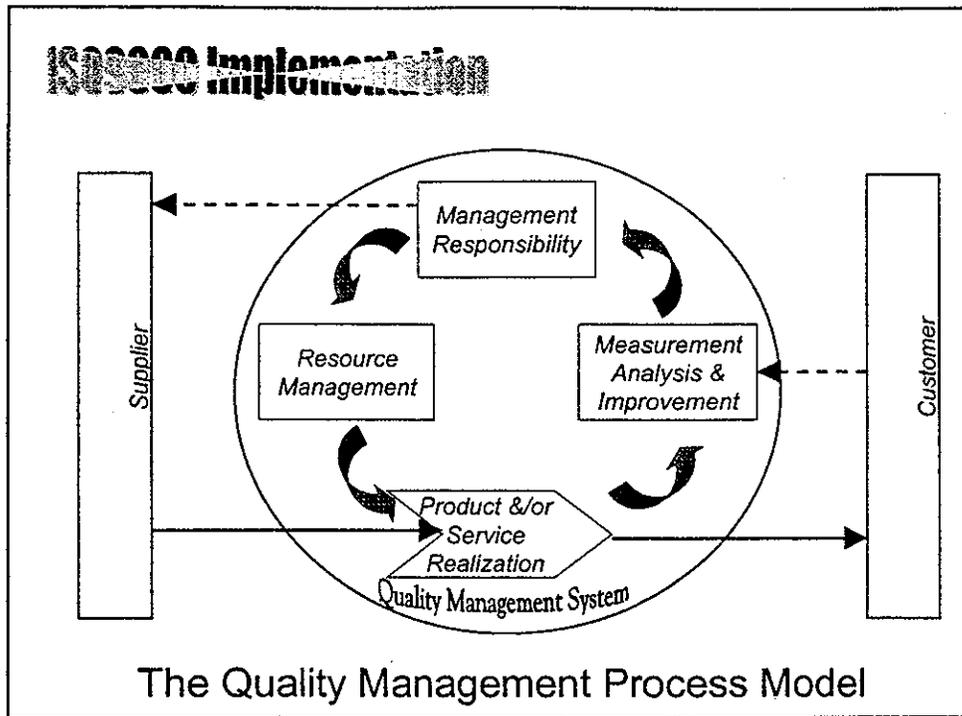
Quality & ISO9000

The Interpretation of ISO9000
The standard specifies
What management must do
But not how they must do it

Tips on interpreting ISO9000 requirements...
Use common sense.
The standards imply that quality must be assured and **CONSISTENTLY** achieved.
Bear in mind the consequences of a problem arising because of inadequate control.
Establish overall confidence in the underlying workings of the system.



Part 2: ISO9000 Implementation Training Module



ISO 9000 Implementation

Phase 1. This phase sets the scene for the remaining phases. The intention is to secure top management common understanding, involvement & commitment.

Action:

- 1.1. Acceptance of the QMS concept outline in ISO9004/1/2/3.
- 1.2. Senior management awareness training on ISO9000.
- 1.3. Set up an implementation steering committee.
 - 1.3.1. Carry out preliminary planning.
 - 1.3.2. Establish your policy on consultants.
 - 1.3.3. Develop a way of measuring progress.
- 1.4. Steering committee training on QMS implementation.
- 1.5. Brief management staff on the QMS implementation program.
 - 1.5.1. Communicate your progress.
- 1.6. Perform gap-analysis.
- 1.7. Report on the gap-analysis findings.
 - 1.7.1. Generate actions to address the 'gaps'.
 - 1.7.2. Modify the QMS implementation program to include these actions
- 1.8. Develop the organization's Quality Policy.

ISO 9000 Implementation

Phase 2. This phase is intended to put in place the mechanisms required to assure the degree of acceptance and ownership necessary to secure the successful implementation of the program.

Action:

- 2.1. Appoint a Quality Management Representative.
- 2.2. Set up the organization structure for the QMS.
- 2.3. Conduct QMS awareness training for selected trainor within the organization.
 - 2.3.1. Start raising awareness at all levels.

ISO 9000 Implementation

Phase 3. This phase develops and sets the relationship between the Standard and the organization's Quality Policy.

Action:

- 3.1. Draft a Quality Manual to ISO9000 standard.
- 3.2. Review the Quality Manual.
- 3.3. Incorporate the necessary changes to the Quality Manual.
- 3.4. Review of the Quality Manual by the Certification Body, if required
- 3.5. Incorporate Quality Manual changes requested by the Certification Body.

ISO 9000 Implementation

Phase 4. This phase involves the development of the Quality documentation, progressive implementation and on-going compliance auditing of the procedures required to meet the requirements of the Standard.

Action:

- 4.1. Develop the system documentation.
- 4.2. Establish a document control system.
- 4.3. Prepare appropriate procedures and work instructions.
- 4.4. Write the appropriate Quality Plan.
- 4.5. Implement the system and operating procedures progressively.
- 4.6. Nominate and train the first batch of auditors.
- 4.7. Carry out the first round of audits.
- 4.8. Perform post-audit benchmarking audit of system.
- 4.9. Prepare and implement the audit program.

ISO 9000 Implementation

Phase 5. This phase is intended to ensure that the procedures are both fully implemented and effective, and that sufficient evidence has been gathered to prove the credibility of the system to the satisfaction of the Certification Body.

Action:

- 5.1. Implement the procedures in full for a nominated period.
- 5.2. Final review and benchmark audit of the QMS against the Standard.
- 5.3. Perform necessary corrective action.
 - 5.3.1. Revise necessary procedures/ documentation.
- 5.4. Improve the system.
- 5.5. Manage the interface the the Certification Body.
 - 5.4.1. Arrange certification visit by Certification Body.
 - 5.4.2. Certification Visit.

What's the difference between Policies, Processes, Procedures, Work Instructions, and Records?

Policies -

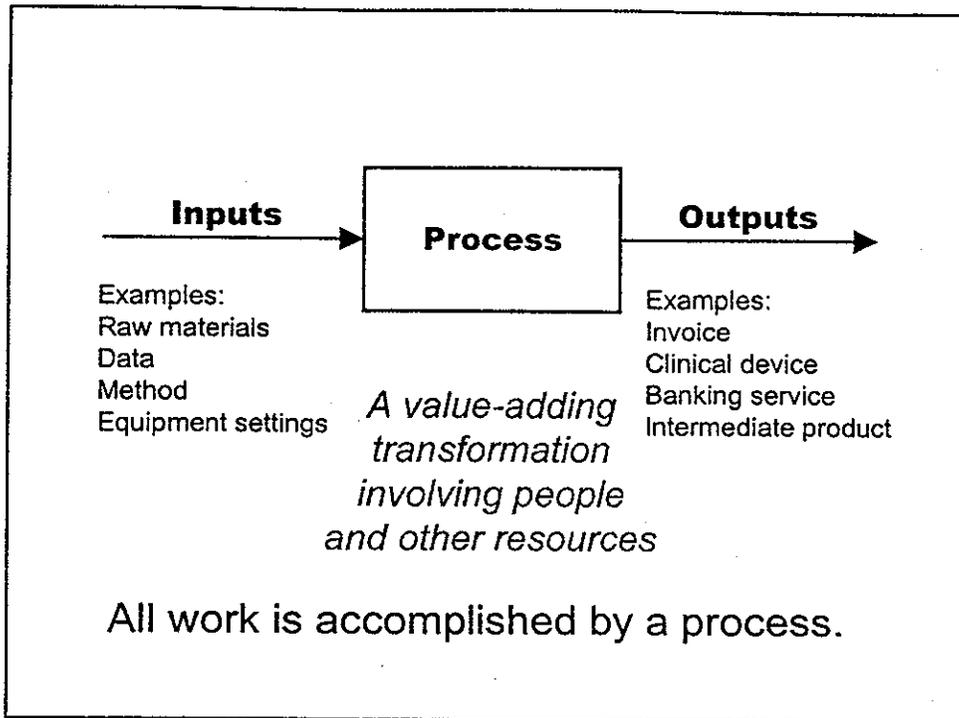
Quality policies are located in the Quality Manual. Policies address our quality objectives and identify the authority and responsible parties. They address the ISO 9000 requirements & identify the implementing procedures.

Processes -

Processes are activities we perform to yield desired outcomes. They are not part of the QMS document hierarchy. They are the core functions our document hierarchy is designed to support.

Procedures -

Procedures are used to document our processes. They describe who, what, when, where and how we carry out our processes. Procedures may have a Center wide scope or their scope may be limited to a particular Directorate, Division, Branch, or Department. They may be tiered such that a lower level procedure provides greater definition as to how an upper level procedure is implemented.



What's the difference between Policies, Processes, Procedures, Work Instructions, and Records?

Work Instructions -

Work instructions are short, precise, step-by-step instructions of a how a particular task is carried out. They are typically applicable to an individual or group of individuals. Work instructions are used when necessary to provide greater detail about a particular task identified within a procedure. They are used to minimize the length of the procedures themselves.

Records -

Records are documents or data items that furnish objective evidence of activities performed or results achieved. Quality records provide traceability and measures for preventive and corrective actions. All quality records associated with a process must be identified in its associated procedure.

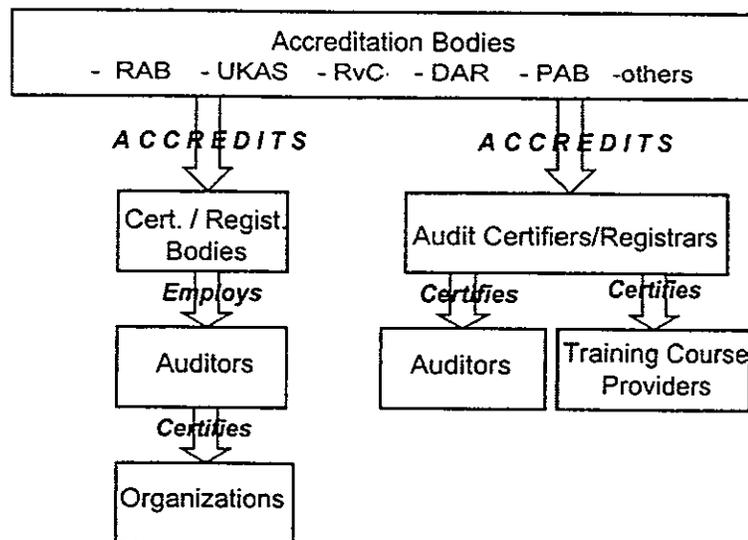
ISO9000 Implementation

The ISO9001/2/3 Certification/Registration Process has three major phases:

- ① Quality system document review
- ② On-site audit
- ③ Assessment analysis and report

ISO9000 Implementation

Functions of Key Organizations Involved in the ISO9000 Certification Process



ISO 9000 Implementation

Achieving Certification / Registration - It's not Magic

- ◆ Most companies already have a system in place.
- ◆ Beneficial to those who do not think it is applicable.
- ◆ Clarify Focus.
- ◆ It's a Process not a Project.
- ◆ Team Effort; not Quality Only.

ISO 9000 Implementation

More benefits that ISO-certified companies report are:

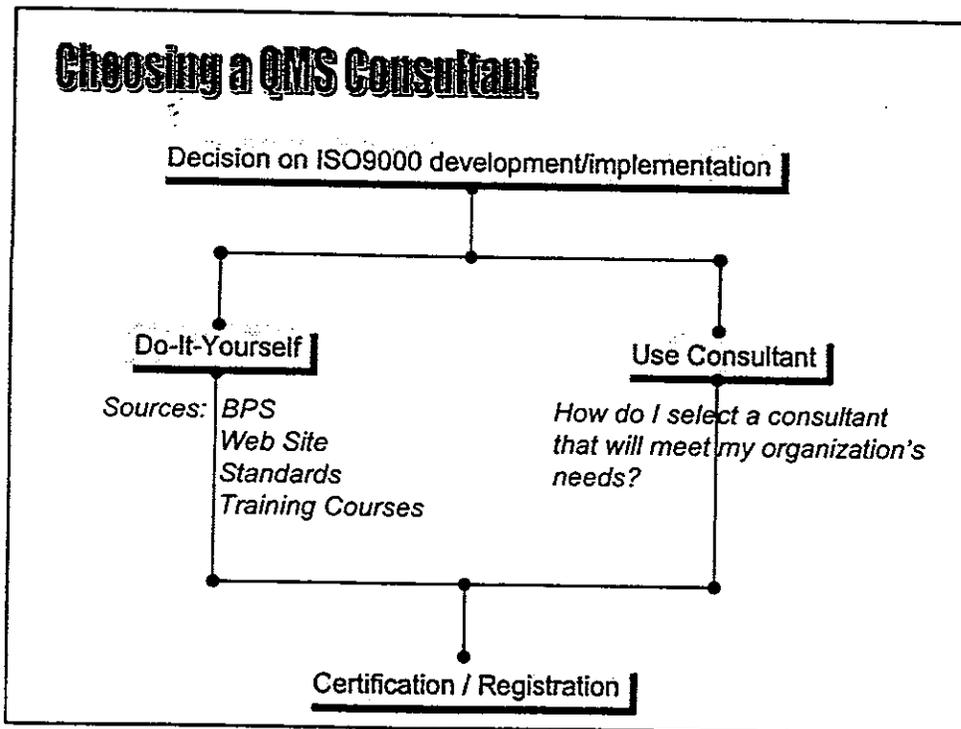
Internally:

Better use of time and resources
Increased efficiency
Less duplication of work
Fewer errors
Less waste
Cost saving
Better motivated employees
Improved communications
Continuous improvements

Externally:

Wider market opportunities
Improved customer confidence
Increased customer satisfaction
Increased competitiveness
Increased market share

Choosing a QMS Consultant



Choosing a QMS Consultant

Guidance on how to select a QMS Consultant:

- A. START
 - A1. State clearly the OBJECTIVE of the consultancy.
 - A2. State the SCOPE.
 - A3. Select the ISO9000 Standard (9004/1/2/3)
- B. Develop a Request for Proposal. Use the following criteria:
 - B1. General Criteria / Commercial Viability
 - Length of time in the business
 - No. of employees
 - No. of clients
 - Company structure
 - Locations
 - Communications

Choosing a QMS Consultant

Guidance on how to select a QMS Consultant:

- B2. Specific Criteria
 - Sector-specific experience
 - Auditor Capability (or access to registered auditors)
 - Competence as demonstrated by:
 - Education level
 - Work experience
 - Training
 - Continuing Professional Development
(Also look for collective competence)
- B3. PLAN - Performance-based Contract
 - Systematic
 - Realistic timelines
 - Covers all stages in the process
 - Identifies required resources

Choosing a QMS Consultant

Guidance on how to select a Certification/Registration Body :

- ★ Use the same guidance (for Consultants) but keep in mind that the following questions must also be addressed:
 - ★ *Is the Cert/Reg Body recognized and accepted by my customers?
Is it accredited by a recognized Accreditation Body?*
 - ★ *Is the number of audit man-days comprehensive enough to cover all my operations?*

Some feedback
from ISO users...



ISO 9000 user feedback



Each dollar invested generates at least a four-fold return if the standard is implemented well.

Robert Dore,
Coordinator for Service
Quality, Municipality of
Saint-Agustin-de-
Desmaures, Canada

The aspect of ISO 9000 which appeals to me most is its emphasis on continuous improvement.

Francisco C. Eizmendi,
Jr., President & COO,
San Miguel Corporation,
Phils.

ISO 9000 user feedback



ESCAP has recognized ISO 9000 as the instrument to help speed economic, technological and social progress in the developing Asia-Pacific countries.

Sohrab, principal
consultant to the U.N.
on the status of ISO
9000 among the
countries of the
Economic and Social
Commission for Asia &
the Pacific (ESCAP)

Our home delivery service has improved so much that the complaints have dropped to a mere 0.06% of the total copies distributed.

Antonio Carlos Macarini,
Industrial & Circulation
Director, Fohla de
Londrina, Brazil

ISO 14000 user feedback



Baxter Healthcare's adherence to ISO 14001 will definitely help to sustain our long-term competitiveness, as discerning customers around the world are becoming more environmentally conscious.

Jay Rajangam, Sr.
Environmental Engineer,
(Singapore unit of)
Baxter Healthcare, USA

ISO 14000 user feedback



It makes good business sense to implement an environmental management system in our plant. In the long run, it will give rise to many benefits. These include protection of the environment and cost savings for the company.

Takeo Kaji, Managing
Director, (Singapore unit
of) Sony Display Device,
Japan

ISO 14000 user feedback



Conformity to ISO 14001 requirements is being maintained without any special effort, as the implemented procedures seem so natural. The continuous improvement concept, which the standard intends to encourage, has been taken on board and is showing clear results.

Bernard Daloz,
Environmental
Programmes Coordinator,
and Philippi Dumoulin,
Quality and Operations
Support Manager,
(French unit of) Lexmark
International, USA

**Welcome to
IIE training on
ISO 9000 Awareness &
Implementation
(linking ISO 9000 & ISO 14000)**

**Sept. 23-24, 1999
Water front Mactan, Cebu**

SCHEDULE OF TRAINING:

Sept. 23	Thu am	Introduction of IISE Project History / Basic Awareness on ISO 14000
	Thu pm	Quality & ISO 9000
Sept. 24	Fri am	ISO 9000 Implementation guidelines
	Fri pm	Guidelines in choosing consultants ISO User Feedback Basic linkage of ISO 9000 and ISO 14000 Services offered by IISE Evaluation of training

The Industrial Initiatives for a Sustainable Environment

**Presented by Jacqui Limtin
QEMS Program Coordinator
IISE**

Overview of IISE

- **Major features**
- **Goal**
- **Project Organization**

Project Organization

- **Implementation sites:**
 - **Focus in the Visayas and Mindanao**
 - **Eight sites - five approved (Cebu, Tagbilaran, Davao, General Santos, CDO); three additional to be selected**
- **Industrial sectors prioritized**
 - **Selection based on level of risk to environment and human health**

Technical Presentation Overview

- **History of Environmental Management Systems and ISO 14000**
- **IER Project Flow Chart**
- **Linkages between ISO 9000 and ISO 14000**

History of Environmental Management Systems

Management systems gave rise to quality management systems which, in turn, gave rise to environmental management systems

– “QMS”; “EMS”; “TQEM”

- **Environmental management systems are private sector-led**
- **All EMS programs worldwide have been intentionally designed and implemented by and for industry**

ISO Definition of EMS

“The part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining the environmental policy.”

Components of an Environmental Management System

- **Programs that address company environmental policies, statements and procedures;**
- **Environmental policy statements, by-laws and codes of behavior of professional and trade associations that a company or an employee is a member of;**

Components of an Environmental Management System

- **Regulatory and legal tracking systems;**
- **Organizational structure within the company;**
- **Environmental relationships with subsidiaries and other plants;**
- **Environmental relationships with suppliers, vendors and subcontractors;**

Components of an Environmental Management System

- **How environmental information flows “vertically” and “horizontally” within the company;**
- **Policy of top management support for environmental programs;**
- **Relationships between top management and staff regarding environmental programs;**

Components of an Environmental Management System

- **Written and communicated job descriptions for all personnel with responsibilities related to environmental affairs;**
- **Plans for implementation of corrective action procedures in cases of procedural breakdown;**
- **All environmental training programs;**

Components of an Environmental Management System

- **Community, citizen, and non-governmental organization outreach programs;**
- **Emergency response planning and procedures;**
- **Records retention policies and policies;**
- **Procedures which address quality assurance and quality control of analytical data.**

History of ISO 14000

ISO 9000 (Quality Management Systems)

- 1991: Strategic Advisory Group on the Environment (“SAGE” - business led)**
- Formation of TC 207**

- Development of ISO 14000 Series**

- 14001/4: Environmental Management Systems**
- 14010-12: Environmental Auditing**
- 14020: Environmental Labeling**
- 14031: Environmental Performance Evaluation**
- 14040: Life Cycle Analysis**

Quality & Environmental Management System Linkages Component

- “2-step” EMS approach
 - Based on the results of the IER, organizations that implement QMS (ISO 9000) prior to EMS (ISO 14000) are identified

Quality & Environmental Management System Linkages Component

- “1-step” EMS approach for organizations that are already ISO 9000 certified or aligned or have been identified to be ready to implement EMS even without ISO 9000
 - Provides linkage to ISO 14000