

CEAA 2002

Management System Design using the “Three Step Process- Identify, Insure, Improve™” ©

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Training, Consulting, Auditing

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Career Highlights:

- Auditor/Consultant/Speaker/Writer/Trainer in ISO 14001 & ISO 9001 Management Systems and Auditor Training.
- Certified Environmental Auditor: CEAA, BEAC, IEMA
- Writer - book “ ISO 9001 - Quality Management Systems”, The Pilot Guide to Implementation” - Specialty Technical Publishers
- Trainer - onsite, on-line internet based. Developed first ISO 14001 training 1995 i.e. Registrars, Government, Industry.
- Past Director CEAA, Member of US - Board of Environmental Health & Safety Certification Board
- 17+ years Environment, Quality, Health & Safety Management Work Experience, 28 years in business development.
- Past District Manager for Fortune 500 waste disposal company, initiating International firsts - medical waste, international waste.



Abstract

This paper will cover the two main management systems that today, impact our businesses globally, the International Standards updated Quality Management Systems requirements for ISO 9001:2000, and the Environmental Management System Standard ISO 14001:1996 and how they can be implemented with the “Three Step Process” to compliment each other, saving time and money in implementation.

Pilot’s “Three Step Process” has been used by industry and government since 1995 and has provided the guidance for implementation of management systems to International Standards for hundreds of organizations.

These steps have been covered in the author’s new book “ISO 9001 - A Complete Implementation Guide”.



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Areas Covered



- ♦ ISO System Standards
 - ♦ Three Step Process
 - Identify, Insure, Improve
- ISO 14001:1996**
ISO 9001:2000



What is the purpose of International Standards?

What benefits are these management systems to my organization?




How can my company be able to implement them in a cost effective manner?

**“Three Step Process
Identify, Insure, Improve™” ©**



ISO 14001 & ISO 9001

Purpose

ISO 9001:1994	ISO 14001:1996	ISO 9001:2000
<ul style="list-style-type: none"> - Means for supplier (organization) to provide to customer organizations, a demonstration of performance of objectives for quality. 	<ul style="list-style-type: none"> - Provide organizations with the elements of an effective EMS which can be integrated with other management systems. - Assist organizations to implement and improve their environmental and economic goals. - continual improvement - prevention of pollution 	<ul style="list-style-type: none"> - Organization provides consistent product meeting customer and regulatory requirements - Enhance customer satisfaction including processes for continual improvement
		

ISO 14001 and ISO 9001 Comparisons

Series	ISO 9000:1994 2 nd Edition	ISO 14000:1996	ISO 9000:2000 3 rd Edition
Requirement document	9001-design* 9002- production* 9003-inspection/test*	14001	9001
Guidance document	9004:1994	14004	9004:2000 (QMS – Guidelines for performance improvements)

*** All three under one Standard ISO 9001:2000**



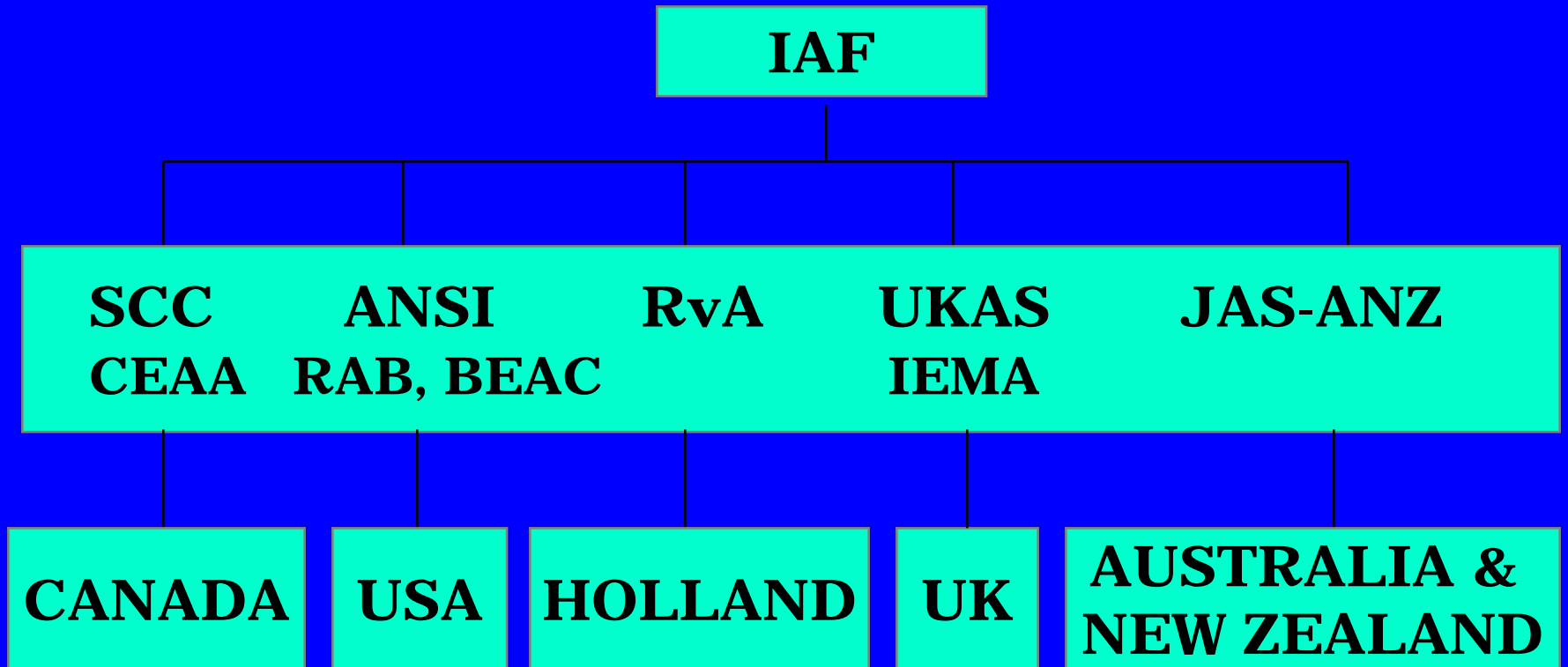


International Organization for Standardization

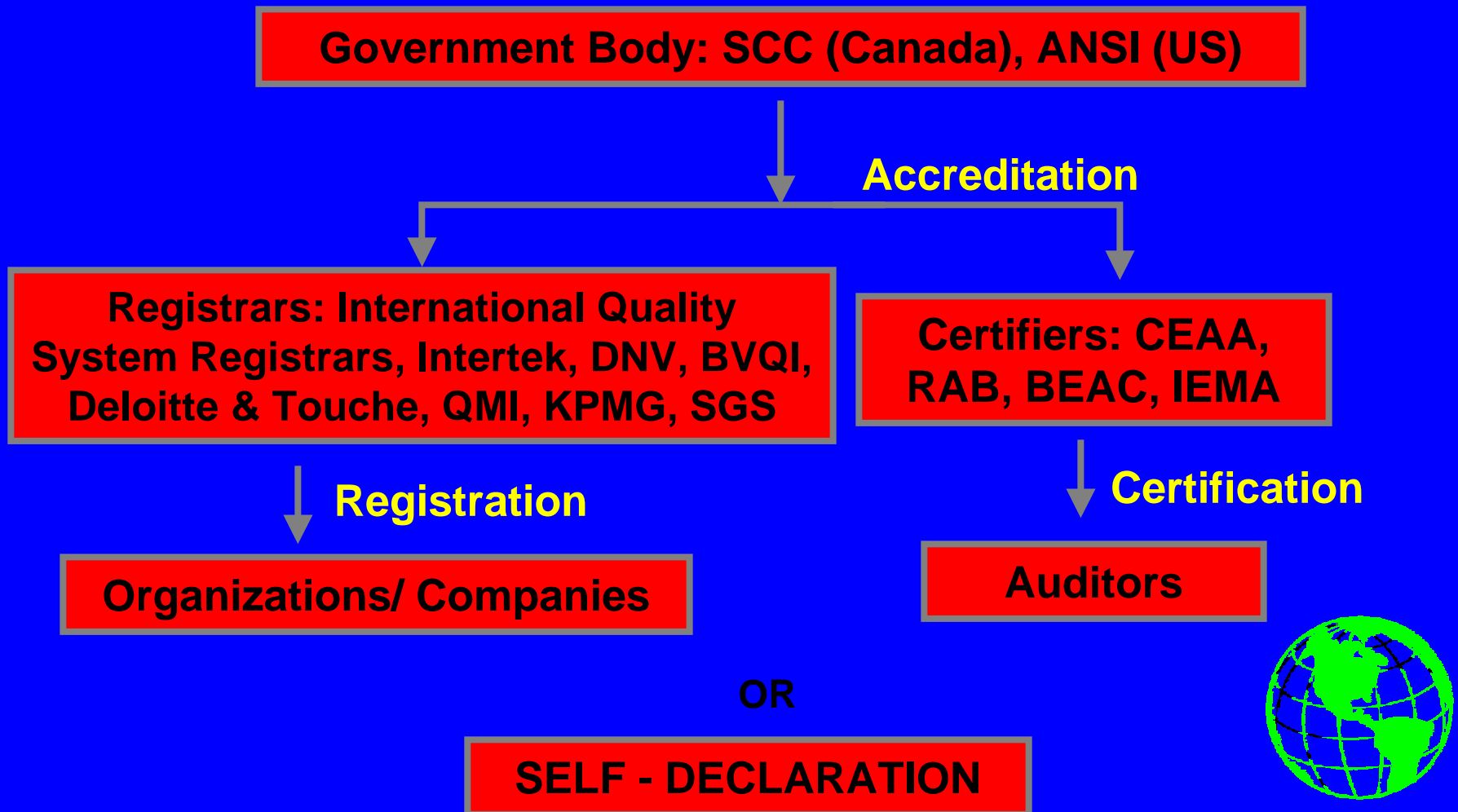
- ♦ Founded in 1947
- ♦ Non-governmental organization based in Geneva
- ♦ Made up of national standards institutes and organizations - 130 countries
- ♦ ISO develops standards of international manufacturing, trade and communications, except those related to electrical and electronic engineering.



Environmental Accreditation Bodies



EMS Structure



ISO 14001 & ISO 9001

ISO 14001 - Environmental Management Systems:



The evolving needs of society for environmental protection

The need for corporations to attain continual improvement & prevention of pollution in environmental management

ISO 9001 - Quality Management Systems:

Achieve customer satisfaction for Quality
Process management and control
Infrastructure of quality to support processes and system improvements



Why Business is Considering ISO

- ◆ Consumers want companies to provide a quality and/or environmentally-friendly product.
- ◆ Public wants assurance that the manufacturing process is managed properly
- ◆ Financial institutions and insurance companies want assurance of management of risk
- ◆ Image of the Company related to Quality and/or Environmental Management is at the forefront internationally. ISO 14001 & ISO 9001 are recognized management system standards.



Why Business is Considering ISO

- Assists company in managing more cost effectively
- Improves the company's operation
 - Identifying environmental aspects, processes, systems, responsibilities, legal requirements, operations, improvements
 - Identifying quality control plans
- Decrease costs and improves the bottom line
- ISO systems provide consistency in approach - increasing efficiency and effectiveness
- Pilot's 3 P's - Performance, Productivity and Profits



Growth of ISO 14001 Certificates

**“ISO Survey of ISO 9000 and ISO 14000 Certificates”
10th cycle - 2000**

Number of Certificates worldwide - 22,897, increase of 8,791

Top Six countries:

<u>Country</u>	<u>Increase</u>	<u>Total Certificates</u>
Japan	2,541	5,556
United Kingdom	1,042	2,534
Sweden	519	1,370
USA	406	1,042
Netherlands	381	784
Australia	341	1,049



Highest Industrial Sector Certificates - ISO 14001

- **Electrical and optical equipment – 3,100**
- **Chemicals, chemical products & fibres – 1,737**
- **Basic metal & fabricated metal products – 1,105**
- **Construction – 1, 035**
- **Food products, beverages and tobacco – 834**



Growth of ISO 9001 Certificates

“ISO Survey of ISO 9000 and ISO 14000 Certificates”

10th cycle - 2000

Number of Certificates worldwide - 408,631 increase of 64,988

Top Six countries:

<u>Country</u>	<u>Increase</u>	<u>Total Certificates</u>
China	10,548	25,657
Italy	9,298	30,367
Japan	6,765	21,329
Republic of Korea	3,891	15,424
Spain	3,877	12,576
Czech Republic	2,355	3,885



Highest Industrial Sector Certificates - ISO 9001

- **Basic metal & fabricated metal products – 40,713**
- **Electrical and optical equipment – 38,148**
- **Construction – 32,389**
- **Machinery and equipment – 23, 027**
- **Wholesale & Retail trade; repairs of motor vehicles, motorcycles and personal and household goods – 18,530**
- **Rubber & Plastic products – 18,036.**



ISO 9001

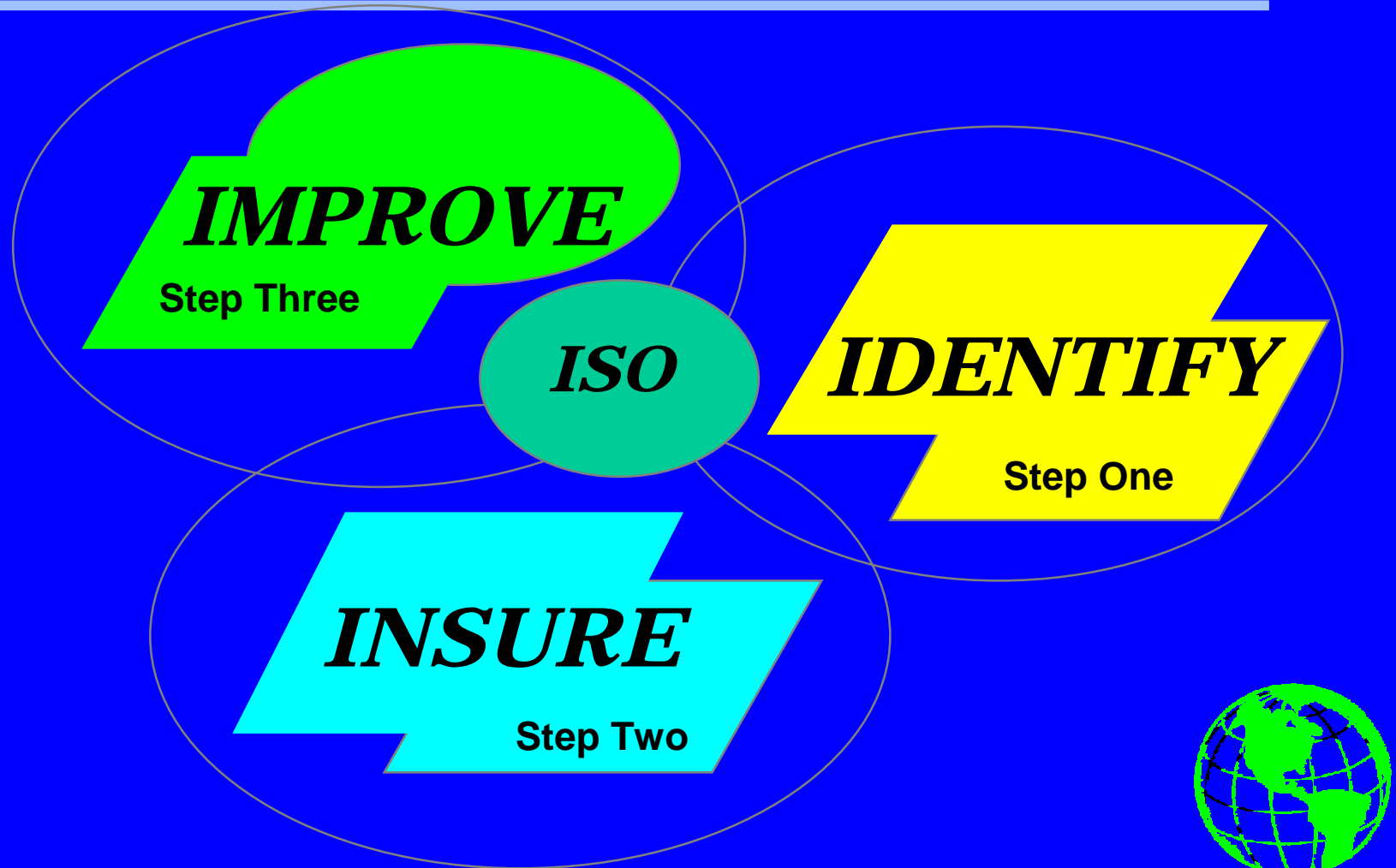
North American Certificates

In North America 48,296 certificates were given

- **United States 35,018**
- **Canada 11,435**
- **Mexico 1,843**



Three I's Model for ISO



ISO 14001

Environmental Management System



What is ISO 14001?

- International voluntary standard
- Developed by the International Organization for Standardization
- Guide organizations in managing and controlling the impacts its products, services and operations have on the environment
- ISO 14001 is the document that organizations can be audited against through registration or self-declaration



Environmental Management System

“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.”



3.2 Environment

“Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation.

Note:

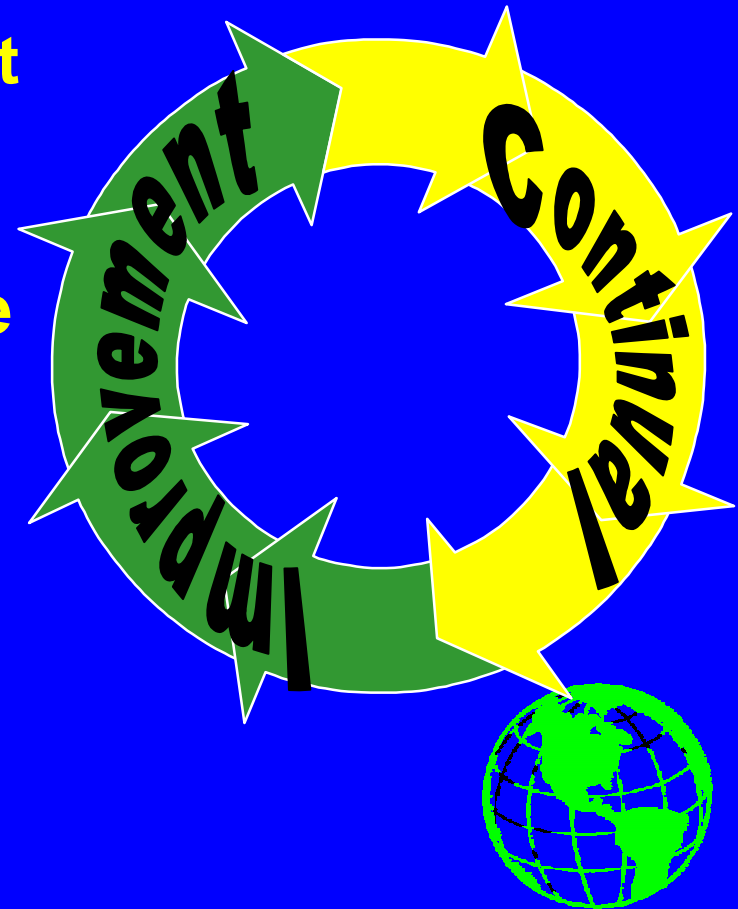
surroundings in this context extend from within an organization to the global system.”



3.1 Continual Improvement

“Process of enhancing the environmental management system to achieve improvements in overall environmental performance in line with the organization’s environmental policy.

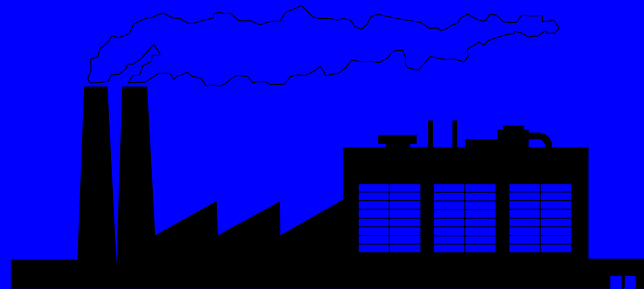
Note: the process need not take place in all areas of activity simultaneously.”



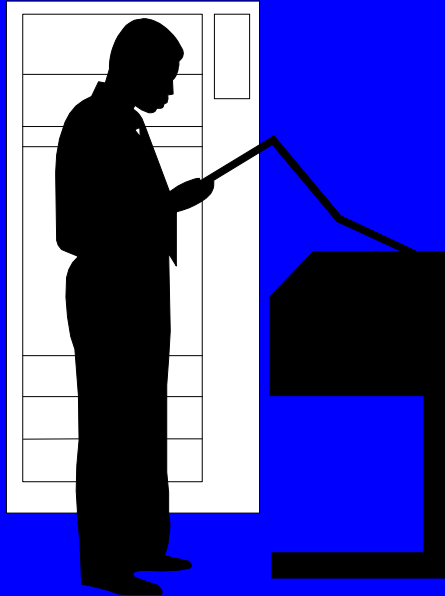
3.13 Prevention of Pollution

“Use of processes, practices, materials or products that avoid, reduce or control pollution, which may include recycling, treatment, process changes, control mechanisms, efficient use of resources and material substitution.”

Note: the potential benefits of prevention of pollution include the reduction of adverse environmental impacts, improved efficiency and reduced costs.”



3.8 Environmental Performance



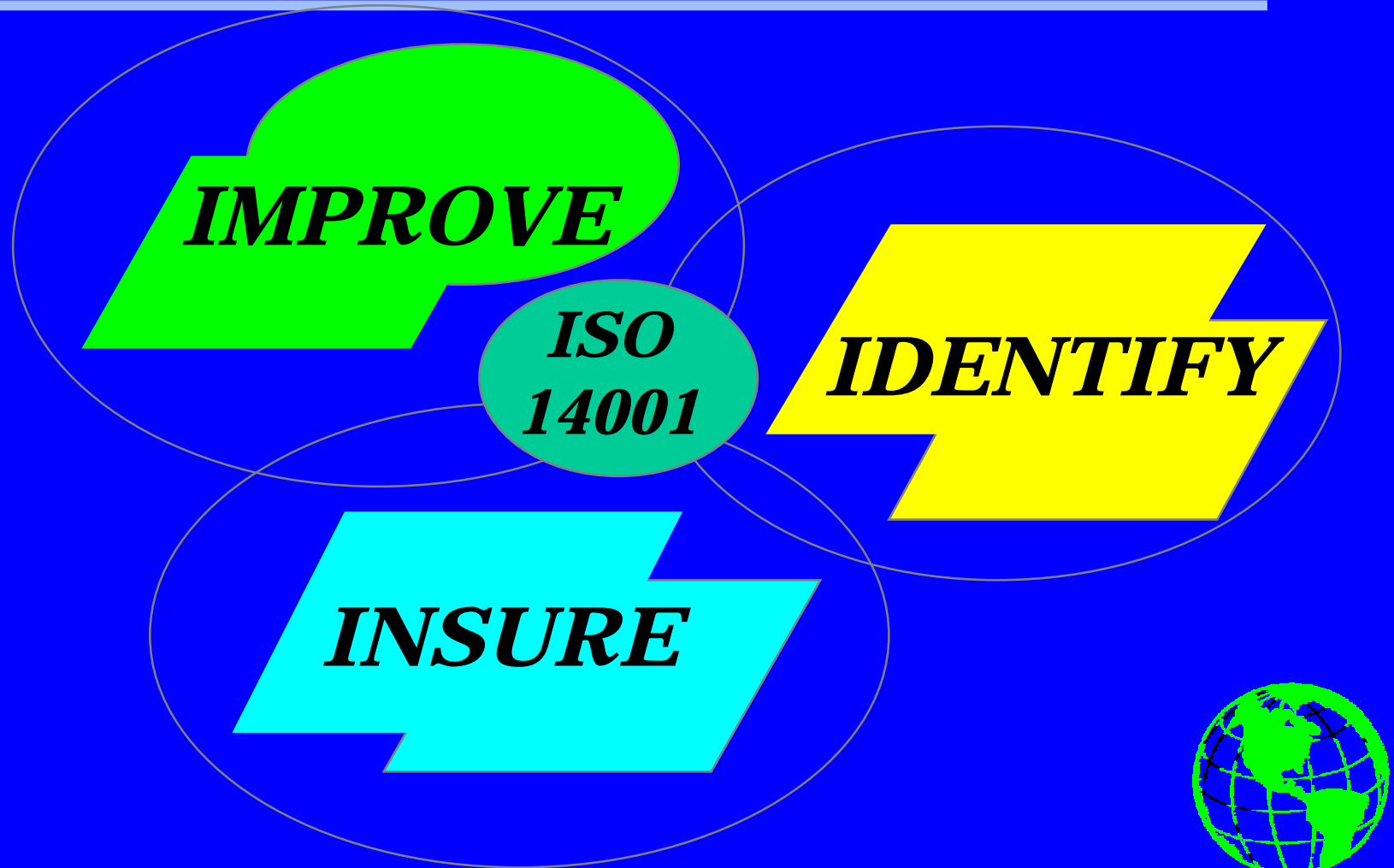
“Measurable results of the environmental management system, related to an organization’s control of its environmental aspects, based on its environmental policy, objectives and targets.”



Environmental Management System Model

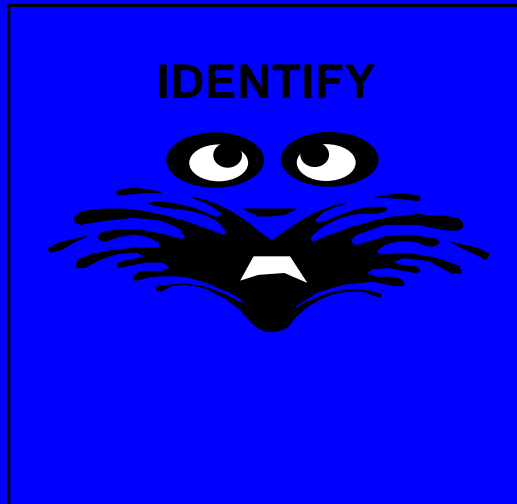


Three I's Model for ISO 14001



ISO 14001

Step One - IDENTIFY



- ☐ Need for EMS
- ☐ Commitment - top management
 - EMS Representative
- ☐ Training on Standard and Implementation
- ☐ Preliminary Review - Environmental Aspects/Impacts of activities/products/service
- ☐ Legal and Other Requirements - standards, permits, codes of practice
- ☐ Planning
 - Policy
 - Objectives and Targets
 - Programs
- ☐ Resources required:
 - People, financial, technological



Significant Environmental Activity/Aspects Diagram

AIR EMISSIONS

- Boilers, Stack, Vehicles, Indoor Air Quality, Filtration Systems, Air Pollutants, Confined Space

TRANSPORTATION

- Waste

EMERGENCIES

- Explosions, Fires
- Natural Disaster
- Spills, Clean-Ups

WASTE MANAGEMENT

- Treatment - Landfill
- Conventional Waste
- Recycling Materials
- By-products
- Special Waste – Medical Waste/Radioactive
- Liquid Chemical

Waste Industry

HAZARDOUS MATERIALS MANAGEMENT

- AST/UST – Gasoline, Chemical, Waste
- Chemical Storage, Collection, Process

WATER

- Condenser Cooling Water
- Neutralization Sump
- Wastewater Discharge
- Sewage Treatment
- Sanitary Sewer
- Oil/water Separator

NOISE/ DUST/ODOUR EMISSIONS

RESOURCE CONSUMPTION

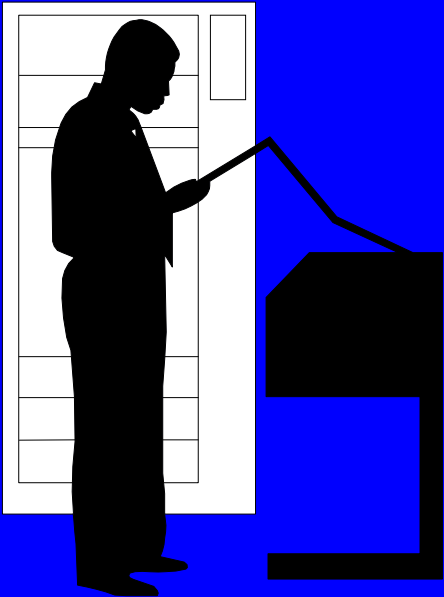
- Utilities/Water/Consumption
- Raw Materials

LAND MANAGEMENT

- Spills, Soil Sampling
- Acid Generation/Drainage
- Contaminated Site
- Property Acquisitions

Step Two - Insure

Insure - means to take out or issue insurance on, to ensure.

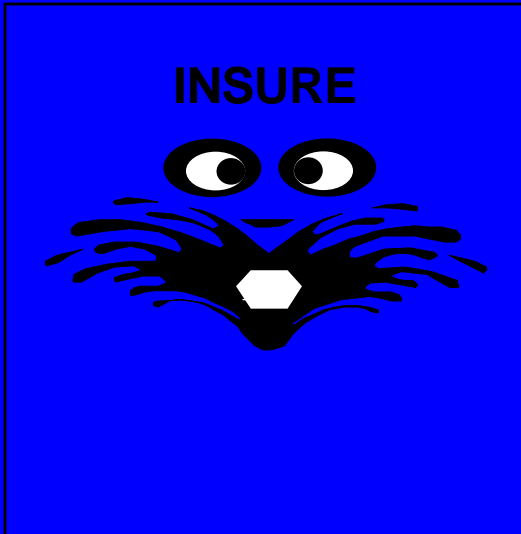


An EMS system insures that a company puts a management system in place, following what they identified as their policy and plans, to control their operations.



ISO 14001

Step Two - INSURE

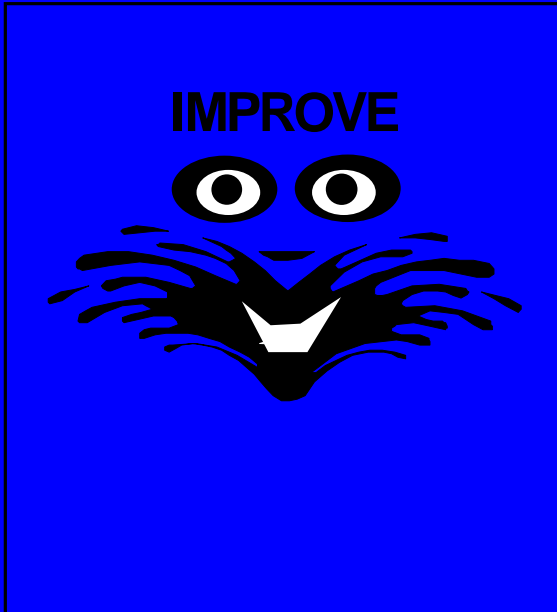


- ☐ Documentation:
 - EMS Manual, Procedures
 - Records (CYA)
- ☐ Structure & Responsibility defined, documented, communicated
- ☐ Operational Control
- ☐ Emergency Response
- ☐ Communication
- ☐ Training
- ☐ Monitoring & Measurement
 - Compliance audit, calibration
- ☐ Nonconformance(s),
Corrective/Preventive Action



ISO 14001

Step Three - IMPROVE



- ☐ Internal Environmental Audit
 - Corporate Requirements
 - ISO 14001 elements
- ☐ Management Review
 - Continual Improvement
 - Pollution Prevention
 - Policy, Objectives & Targets
 - Audit Results
- ☐ Third Party Audit
 - Self-Declaration or
 - Registration



ISO 9001

Quality Management System



Purpose - ISO 9000

- **Quality management systems deal with customer needs.**
- **The ISO 9000 series is founded upon the management of the principles of process management and control.**
- **An infrastructure of quality to support processes and system improvement to achieve customer satisfaction by preventing nonconformance at all stages, from design to manufacturing to servicing.**



ISO 14001 & ISO 9001 Comparison - Similarities

ISO 9001:1994	ISO 14001:1996	ISO 9001:2000
<ul style="list-style-type: none"> • Management commitment • Responsibility • Documentation & control • Operational control • Training • Monitoring & measurement • Nonconformance & corrective action • Records • System audits • Management review • Policy 	<p>Includes item in ISO 9001:1994 and the following:</p> <ul style="list-style-type: none"> • Objectives & Targets • Communication • Legal and Other Requirements • Continual Improvement • System Planning 	<p>Includes item in ISO 9001:1994 and the following:</p> <ul style="list-style-type: none"> • Objectives & Targets • Communication • Legal and Statutory Requirements • Continual Improvement • System Planning

ISO 14001 & ISO 9001 Comparison - Differences

ISO 9001:1994	ISO 14001:1996	ISO 9001:2000
quality planning, product identification and traceability, inspection and test status, statistical techniques.	elements of environmental aspects, legal requirements, objectives and targets, environmental management program, communications, emergency preparedness and response.	work environment, product realization, customer communication, design and development, customer satisfaction, Infrastructure, customer focus.

ISO 9000:1994 Elements

- | | |
|--|--|
| 4.1 Management Responsibility | 4.12 Inspection & Test Status |
| 4.2 Quality Systems | 4.13 Control of Nonconforming Product |
| 4.3 Contract Review | 4.14 Corrective & Preventive Action |
| 4.4 Design Control | 4.15 Handling, Storage, Packaging, Preservation & Delivery |
| 4.5 Documents & Data Control | 4.16 Control of Quality Records |
| 4.6 Purchasing | 4.17 Internal Quality Audit |
| 4.7 Control of 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 and Testing | |
| 4.11 Control of Inspection, Measuring & Test Equipment | |



ISO 9001:2000 Elements

4.1 General Requirements

4.2 Documentation Requirements

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning

5.5 Responsibility, Authority and Communication

5.6 Management Review

6.1 Provision of Resources

6.2 Human Resources

6.3 Infrastructure

6.4 Work Environment

7.1 Planning of Product Realization

7.2 Customer-related Processes

7.3 Design and Development

7.4 Purchasing

7.5 Production and Service Provision

7.6 Control of Monitoring and Measuring Devices

8.1 General

8.2 Monitoring & Measurement

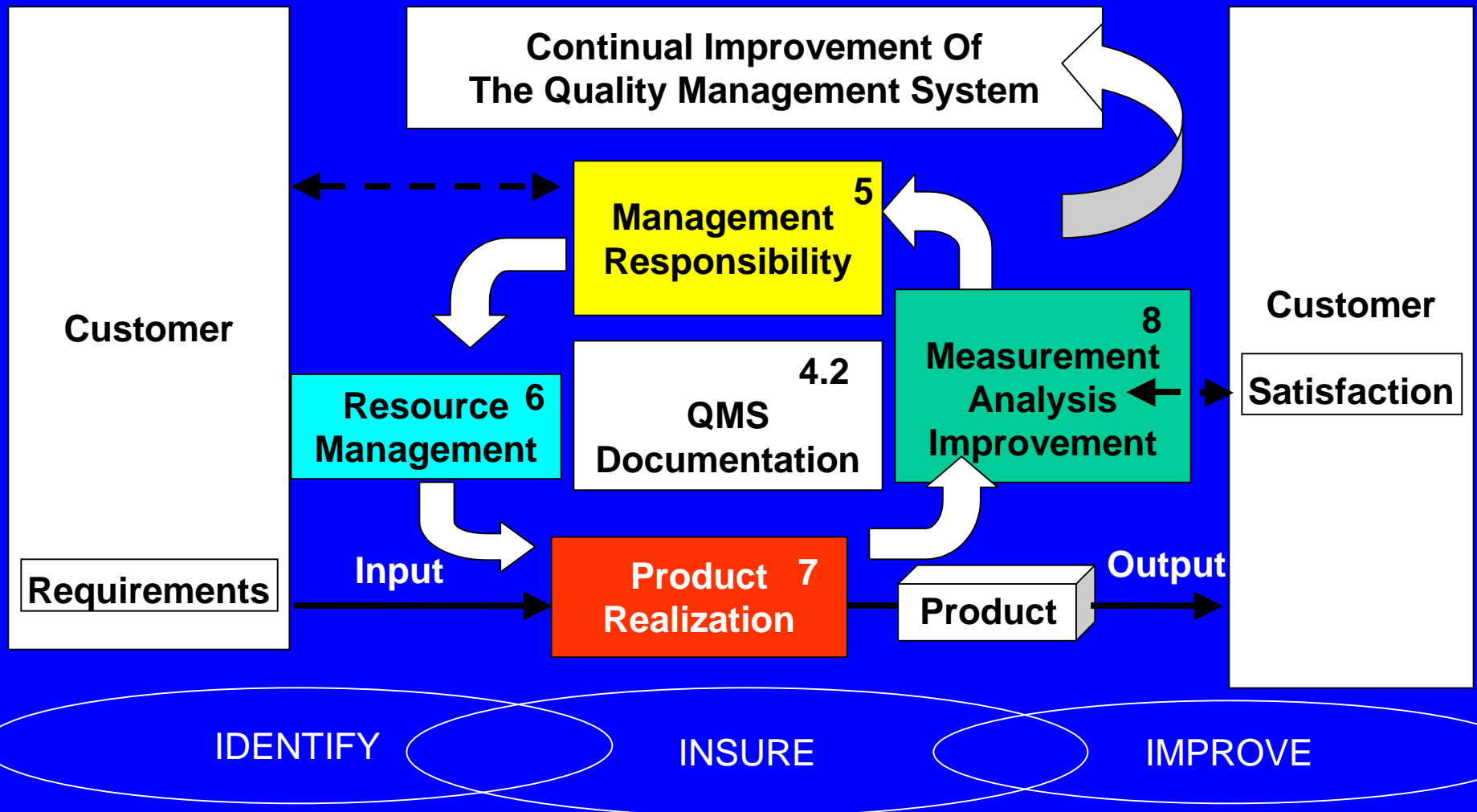
8.3 Control of Nonconforming Product

8.4 Analysis of Data

8.5 Improvement



Three I's Process Model for ISO 9001:2000



ISO 9001:2000 Changes

The changes aim to:

- **Enhance compatibility with the Environmental Management System Standard – ISO 14001**
- **Emphasize customer requirements and the need to monitor customer satisfaction**
- **Make documentation more user-friendly (this was very intensive in the last two editions)**
- **Promote the use of the eight generic principles of Quality Management**



ISO 9001:2000 Changes

Top Management Emphasis:

More emphasis has been placed on top management:

- including commitment to the development and improvement of the QMS with customer focus
- setting of measurable objectives at relevant functions and levels within the organization to insure continual improvement.
- to provide and make available the necessary resources.



ISO 9001:2001 System Model

Company needs to demonstrate that it has a system in place that:

- **Meets customer requirements**
- **Meets applicable regulatory and statutory requirements**
- **Is aimed to enhance customer satisfaction**
- **Includes the process for continual improvement**



Eight Principles for QMS

- Principle 1 Customer Focus**
- Principle 2 Leadership**
- Principle 3 Involvement of People**
- Principle 4 Process Approach**
- Principle 5 System Approach to Management**
- Principle 6 Continual Improvement**
- Principle 7 Factual Approach to Decision Making**
- Principle 8 Mutually Beneficial Supplier Relationship**



Eight Principles for QMS

Principle 1 - Customer Focus

- Understand current and future customer needs. Meet customer requirements, strive to exceed expectations.

Principle 2 - Leadership

- Establish unit of purpose and direction. Create and maintain internal environment for people to be involved in achieving objectives.

Principle 3 - Involvement of People

- All levels of personnel involved providing a beneficial environment.

Principle 4 - Process Approach

- Desired result achieved when activities and related resources are managed as a process



Eight Principles for QMS

Principle 5 - System Approach to Management

- Identify, understand and manage interrelated processes as a system, achieving objectives.

Principle 6 - Continual Improvement

- Continual improvement of overall performance is a permanent objective.

Principle 7 - Factual Approach to Decision Making

- Effective decisions made, based on analysis of data and information.

Principle 8 - Mutually Beneficial Supplier Relationship

- Organization and suppliers are interdependent, enhancing ability of both to create value.

ISO 9000:2000 QMS Fundamentals and Vocabulary



New Areas Added to ISO 9001:2000

- **ISO 9001:2000 aligned with ISO 14001:1996 for compatibility**
- **Terminology**
 - “Supplier” used in ISO 9001:1994 is replaced with “organization” - term also used in ISO 14001
 - “Supplier” is now used in place of “subcontractor”
 - “Product” can also mean “service”
- **New system model based on a process model**
- **Top management commitment to**
 - **Continual improvement**
 - **Consider regulatory requirements**
 - **Establish measurable quality objectives**



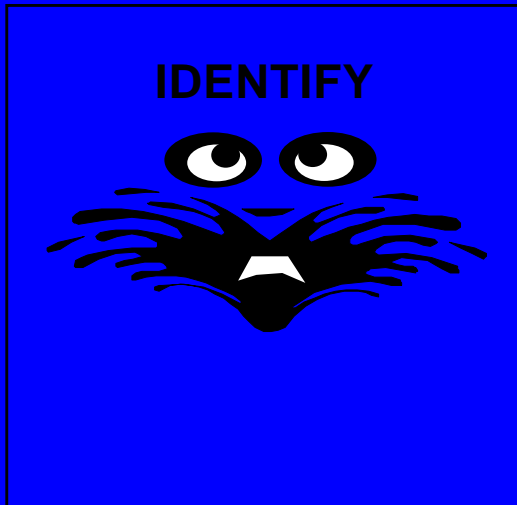
New Areas Added to ISO 9001:2000

- Quality planning improvement implied in ISO 9001:1994, outlined in ISO 9001:2000
- Expanded requirements for top management review
 - Specifying inputs/outputs
 - Evaluating need for changes to QMS, policy, objectives
- Training of personnel - aware of relevance and importance to activities and achievement of quality objectives
- Increase requirements related to facilities, work environment
- Design and development - ensure communication and assignment of responsibility
- Measurement requirements expanded on processes, product and QMS



ISO 9001:2000

Step One - IDENTIFY



- ☐ Need for QMS
- ☐ Commitment - Top Management
 - o QMS Representative
- ☐ Training on Standard and How to Implement. Book: "ISO 9001 A Complete Implementation Guide"
- ☐ Gap Analysis (if required)
- ☐ Requirement Identification
 - o Customer
 - o Processes and their Application
 - o Product Realization - Quality Plans
 - o Design & Development Planning
 - o Legal and Other
 - o Supplier
- ☐ Planning
 - o Policy Statement
 - o Objectives
 - o Resource Management



ISO 9001:2000

Step Two - INSURE

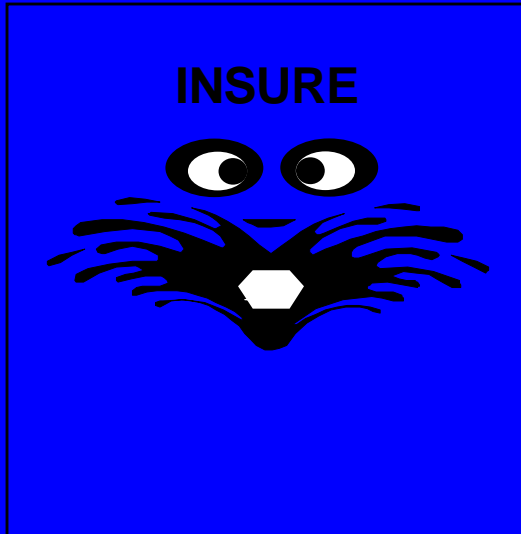


- ☐ Document Requirements
 - QMS Manual, Procedures, Records
- ☐ Management Responsibility
- ☐ Resource Management
 - Competence/Awareness/Training, Infrastructure, Work Environment, Processes
- ☐ Communications
 - Internal, customer
- ☐ Product Realization
 - Design & Development Inputs/Outputs, Review, Verification, Validation, Control of Changes



ISO 9001:2000

Step Two - INSURE

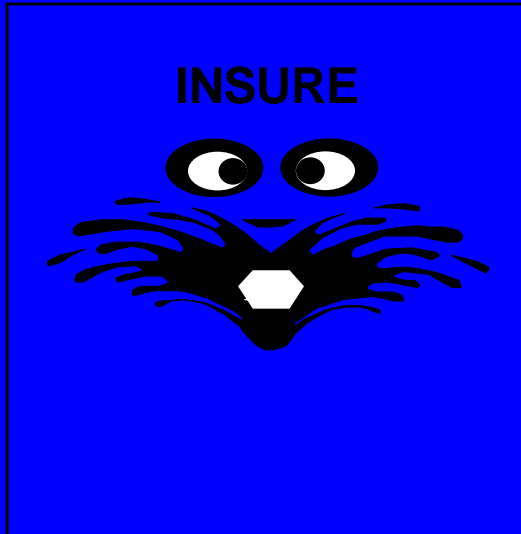


- ☐ Purchasing
 - o Process, Information, Verification
- ☐ Production & Service Provision
 - o Control of Production & Service Provision, Validation of processes, Identification and traceability, Customer Property, Preservation of Product
- ☐ Control of Monitoring & Measuring Devices
- ☐ Measurement, Analysis & Improvement
- ☐ Training - Skills training, QMS training,



ISO 9001:2000

Step Two - INSURE



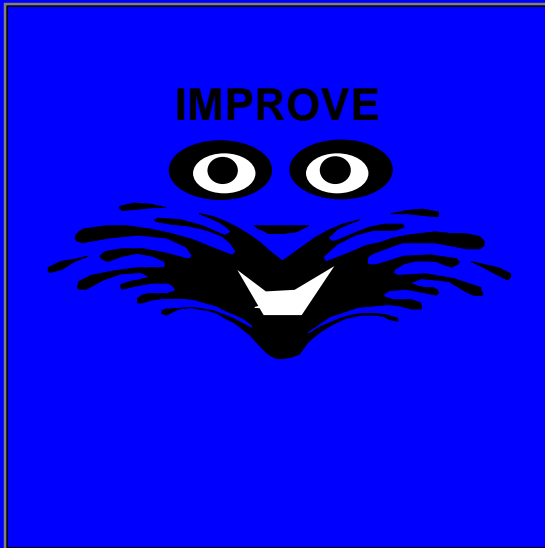
☐ Monitoring & Measurement

- ☐ Customer Satisfaction
- ☐ Processes - quality, statistical techniques, design, nonconformances
- ☐ Product - receiving/in-process/final inspection & test
- ☐ Control of Nonconforming Product
- ☐ Analysis of Data
- ☐ Continual Improvement



ISO 9001:2000

Step Three - IMPROVE

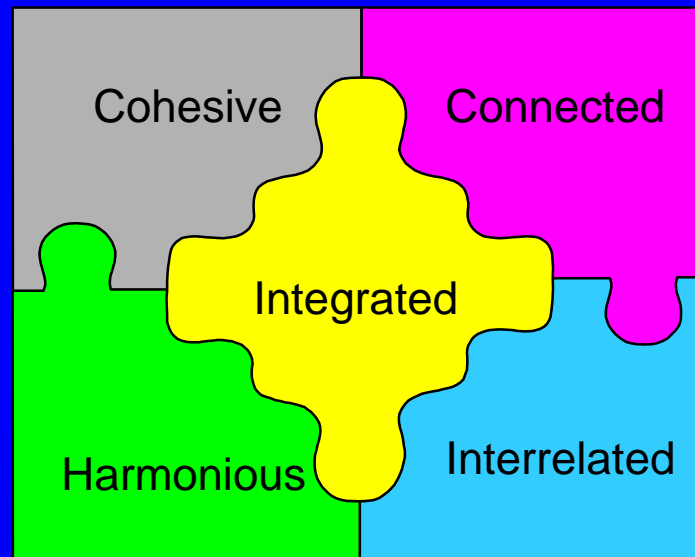


- ☐ **Continual Improvement**
 - Policy, Objectives, Analysis of Data
- ☐ **Internal Quality Audit**
- ☐ **Corrective/Preventive Action**
- ☐ **Management Review**
 - Input - audit results, customer feedback, process performance, product conformity, status of preventive/corrective actions, reviews, changes, recommendations
 - Output - improvement of effectiveness of QMS, processes, product, resource needs
- ☐ **Self-Declaration or Registration**



ISO 14001 & ISO 9001 Integration

Systems can be harmonious, connected, by making reference to areas that are similar - not duplicating documentation. ISO 9001 is not a prerequisite to the ISO 14001 standard.



Conclusion

Edward Deming - Quality Gurus - 1940's key Quality practitioner. A specialist in statistical techniques, working with US Government. In 1960 received Japan's highest imperial honor, the Second Order of Sacred Treasure Award.

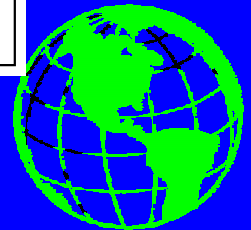
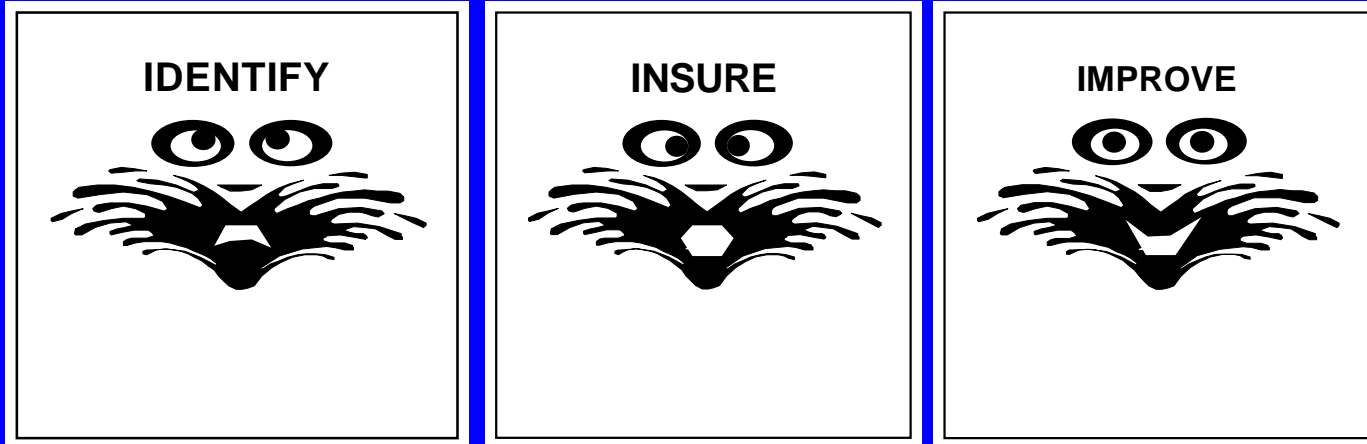
Deming is known for :

“Plan - Do - Check - Act”

Pilot Performance, “Three Step Process” takes management system implementation into the 21st Century with “Identify, Insure, Improve”



ISO Management System “Identify, Insure, Improve” ©



**The EYES (I's)
are
Watching Us
in
Environmental & Quality Management**



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