ISO 9000

What You Need To Know

ISO 9000

What do you need to know about ISO 9000?

What are the ISO 9000 Series Standards? ▶

What are the elements of the Standards? ▶

Why is ISO 9000 so important? ▶

What is quality system registration? ▶

Ten steps to ISO 9000 registration ▶

What are ISO 9000 Standards?

- ISO 9000 Standards

    - Define the required elements of an effective quality management system

    - Can be applied to any company

    - Adopted by the United States as the ANSI/ASQC Q90 series.
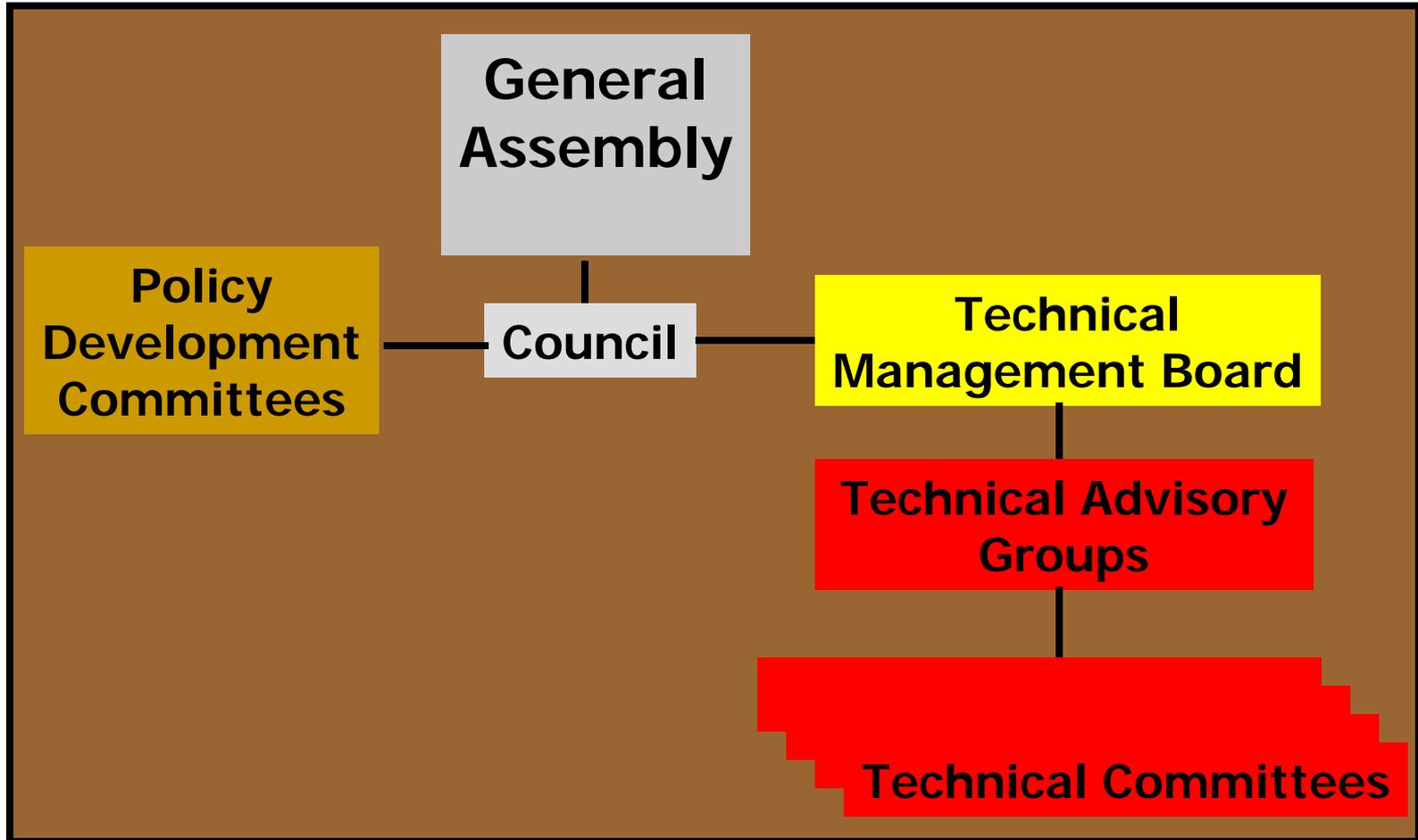
- Revised 2000 – wider applicability

Who created the standards?

- International Organization for Standardization - Geneva

- ISO tech committee - TC 176 started in 1979

- Standards created in 1987

  - To eliminate country to country differences

  - To eliminate terminology confusion

  - To increase quality awareness

How did ISO get started?

- 1906 - International Electro-technical Commission
- 1926 - International Federation of the National Standardizing Associations (ISA)
- 1946 London - delegates from 25 countries decided to create a new international organization "the object of which would be to facilitate the international coordination and unification of industrial standards
- 1947 - ISO began to officially function
- 1951 - The first ISO standard was published
  - "Standard reference temperature for industrial length measurement".

ISO Organization

General Assembly

Policy Development Committees — **Council** — **Technical Management Board**

Technical Advisory Groups

Technical Committees

What has ISO Accomplished?

- *ISO film speed code*
- **Standard** *format for telephone and banking cards*
- *ISO 9000* **which provides a framework for quality management and quality assurance**
- *ISO 14000* **series provides a similar framework for environmental management**
- *Internationally standardized freight containers*
- **Standardized** *paper sizes.*
- *Automobile control symbols*
- *ISO international codes* **for** *country names, currencies and languages*

ISO 9000:2000 Consists of 3 Areas

- ISO 9000:2000 Quality Management Systems: fundamentals and vocabulary

- ISO 9001:2000 Quality Management Systems – Requirements (required for certification)
  - Management responsibility
  - Resource management
  - Product/service realization
  - Measurement, analysis, improvement

- ISO 9004-2000 Quality Management Systems – Guidelines for performance improvement

ISO 9000 Family of Standards

- ISO 8402 - QA and Quality management vocabulary
- ISO 9000-2 - Generic guidelines for applying ISO 9001, ISO 9002, and ISO 9003
- ISO 9000-3 - Guidelines for applying ISO 9001 to the development, supply, and maintenance of software
- ISO 9000-4 Application for dependability management
- ISO 9004-2 Guidelines for services
- ISO 9004-3 Guidelines for processed material
- ISO 9004-4 Guidelines for quality improvement
- ISO 9004-5 Guidelines for quality plans
- ISO 9004-6 Guidelines for configuration management

What are the elements of the standards?

- Management responsibility
- Resource management
- Quality System
- Contract Review
- Design Control
- Document Control
- Purchasing
- Purchaser-Supplied Product
- Product Identification and Traceability
- Process Control

- Inspection and Testing
- Inspection, Measuring and Test Equipment
- Inspection and Test Status
- Control of Non-conforming product
- Corrective Action
- Quality Records
- Internal Quality Audit
- Training
- Servicing
- Statistical Techniques

Element Standard: Management Responsibility

- Management must have a written policy statement of their commitment to quality. This policy must be communicated to and understood by all employees.

- Management must clearly define quality-related organizational responsibilities and interrelationships.

- A management representative must be assigned to oversee the implementation and continuous improvement of the quality system.

- Senior management must continually review the system.

Element Standard:
Process Control

- The company must identify all processes that directly affect the quality of the product or service and ensure that these processes are carried out under controlled conditions, including:

  - Formal approval of process design and equipment.

  - Documented work instructions.

  - Development of quality plans describing how the process is to be monitored.

  - A suitable working environment.

  - Documented quality criteria.

Why is ISO 9000 important?

- European Union directive
  - ISO 9000 certification required by suppliers of "Regulated Products"
    - health, safety, and the environment
  - EC has strict corporate liability legislation protecting consumers
- Globalization impact

Why adopt ISO 9000?

- To comply with customers who require ISO 9000
- To sell in the European Union market
- To compete in domestic markets
- To improve the quality system
- To minimize repetitive auditing by similar and different customers
- To improve subcontractors' performance

Third party registration

ASQC

**Accreditors
(RAB in US)**

Registrars

Supplier Companies

Ten Steps to ISO Registration

10. Registration!

9. Final assessment by registrar

8. Take corrective actions

7. Pre-assessment by registrar

6. Submit quality manual for approval

5. Perform self-analysis audit

4. Select a third-party registrar and apply

3. Develop and implement the quality system

2. Select the appropriate standard

1. Set the registration objective

ISO 9000

Six Essential Elements of a Successful Registration Effort

Senior Management Commitment to the Effort

Appropriate ISO 9000 Training

An Effective Management Review Process

Documentation of the Quality System

An Effective Internal Auditing System

An Effective Corrective Action Process