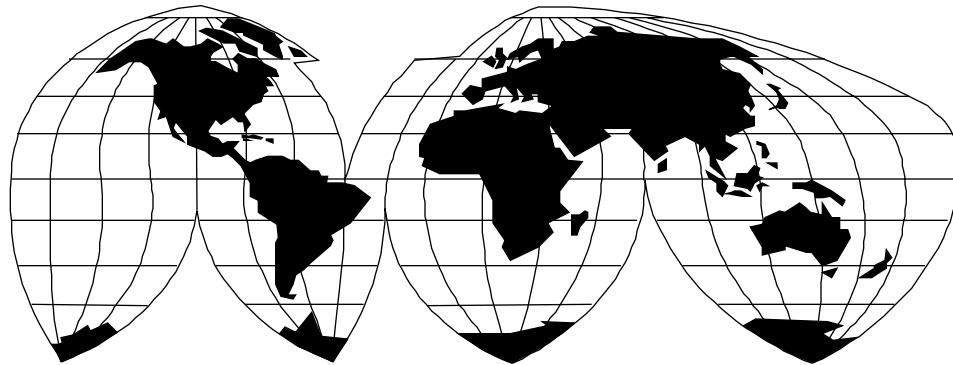


International Quality System Requirements

ISO 9000



1

DYNAMIC INSTRUMENTS, INC.

San Diego, CA

ISO 9000

Dynamic Instruments, Inc.
San Diego, CA 92123

Phone: 619-278-4900

FAX: 619-278-6700

E-Mail: *info@dynamicinst.com*

URL: *www.dynamicinst.com*

2

DYNAMIC INSTRUMENTS, INC.

San Diego, CA



History

USA - DOD

Mil-I-45208

Methods and procedures are a part of the publication and specification

Mil-Q-9858

Mil-Q is a nine page document with policy guidelines

Mil-Q-9858A

The contractor must publish a Quality Manual in accordance with MIL-Q-9858A policy.

3

Who is ISO ?

- **International Organization for Standardization (ISO)** with the goal of promoting standards world wide.
- American National Standards Institute (ANSI) is the US member of the world organization.
- US member was the leader of the committee that authored the ISO 9000 standards.
- Registrar of Accreditation Board (RAB) is the US accreditor council.

What are the ISO 9000 Standards?

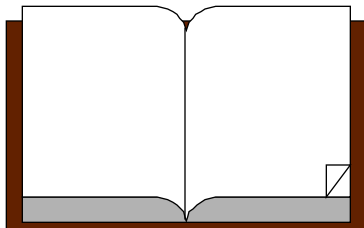
- They are generic and apply to any industry.
- They specify elements of a quality system.
- They do not provide implementation requirements.
- The ISO 9000 Handbook
The Handbook of Quality Standards and Compliance

Handbook of Quality Standards and Compliance

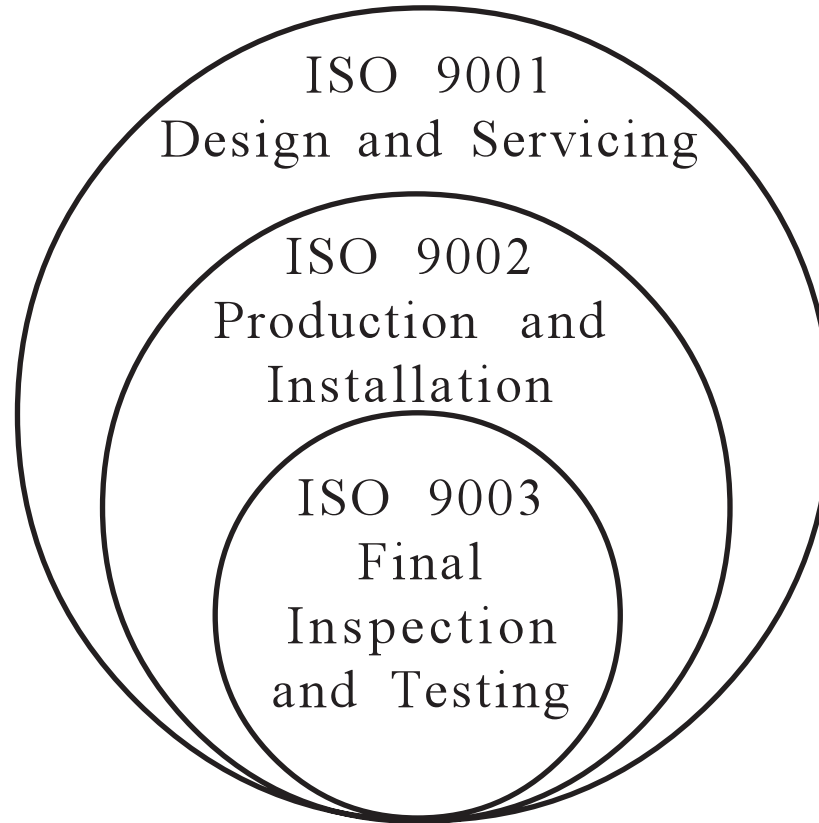
Prentice Hall, Professional Publishing

Englewood, NJ 07632

(one inch thick, 8" x 10")



What are the ISO 9000 Series?



ISO 9000 - Explains which standard should be invoked based upon processes utilized.

ISO 9004 - Gives guidelines and interpretations of the standards.

6

What documentation is required ?

Quality Manual

Description of the
Quality System

Procedures

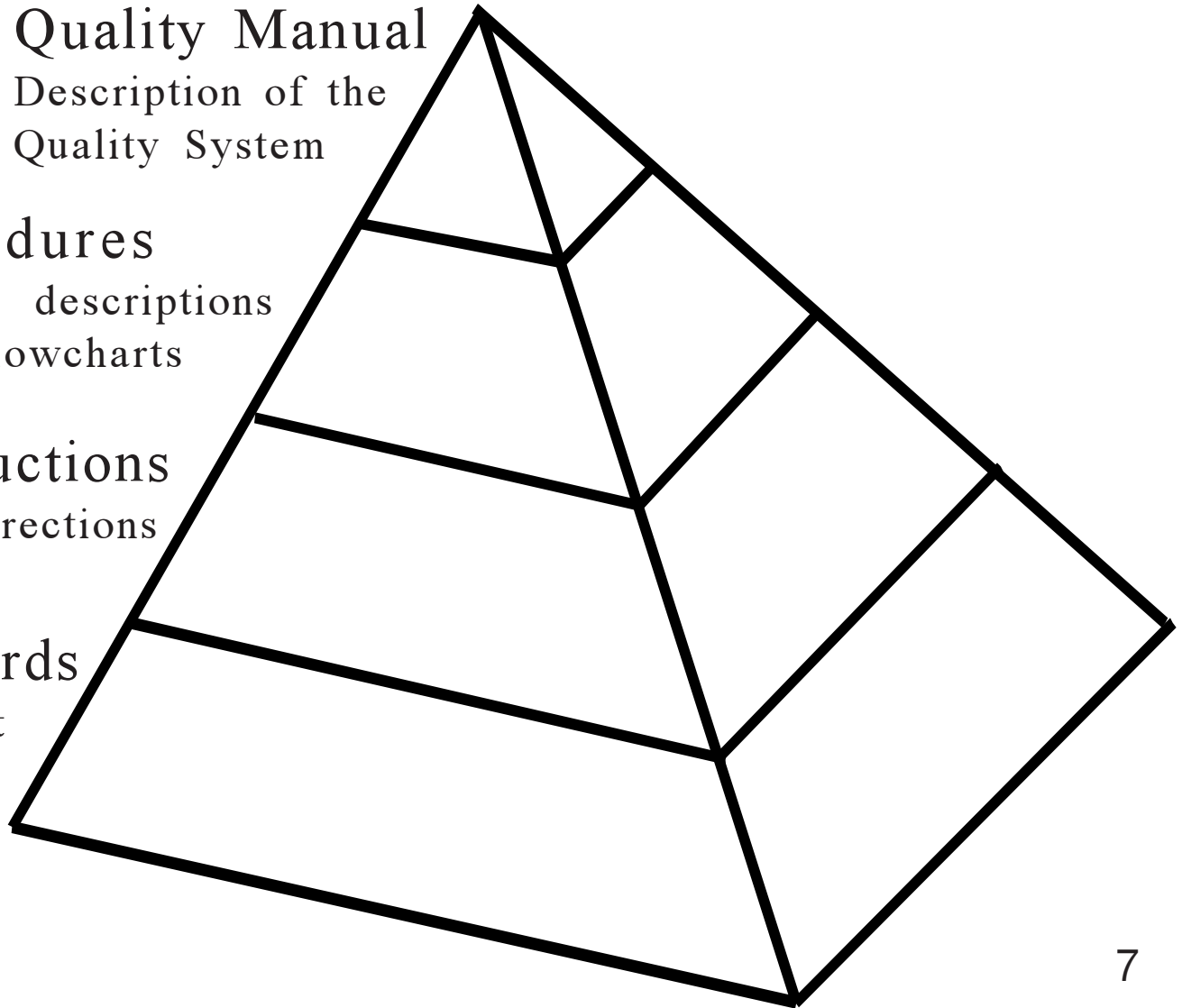
Process descriptions
using flowcharts

Work Instructions

Step-by-step directions

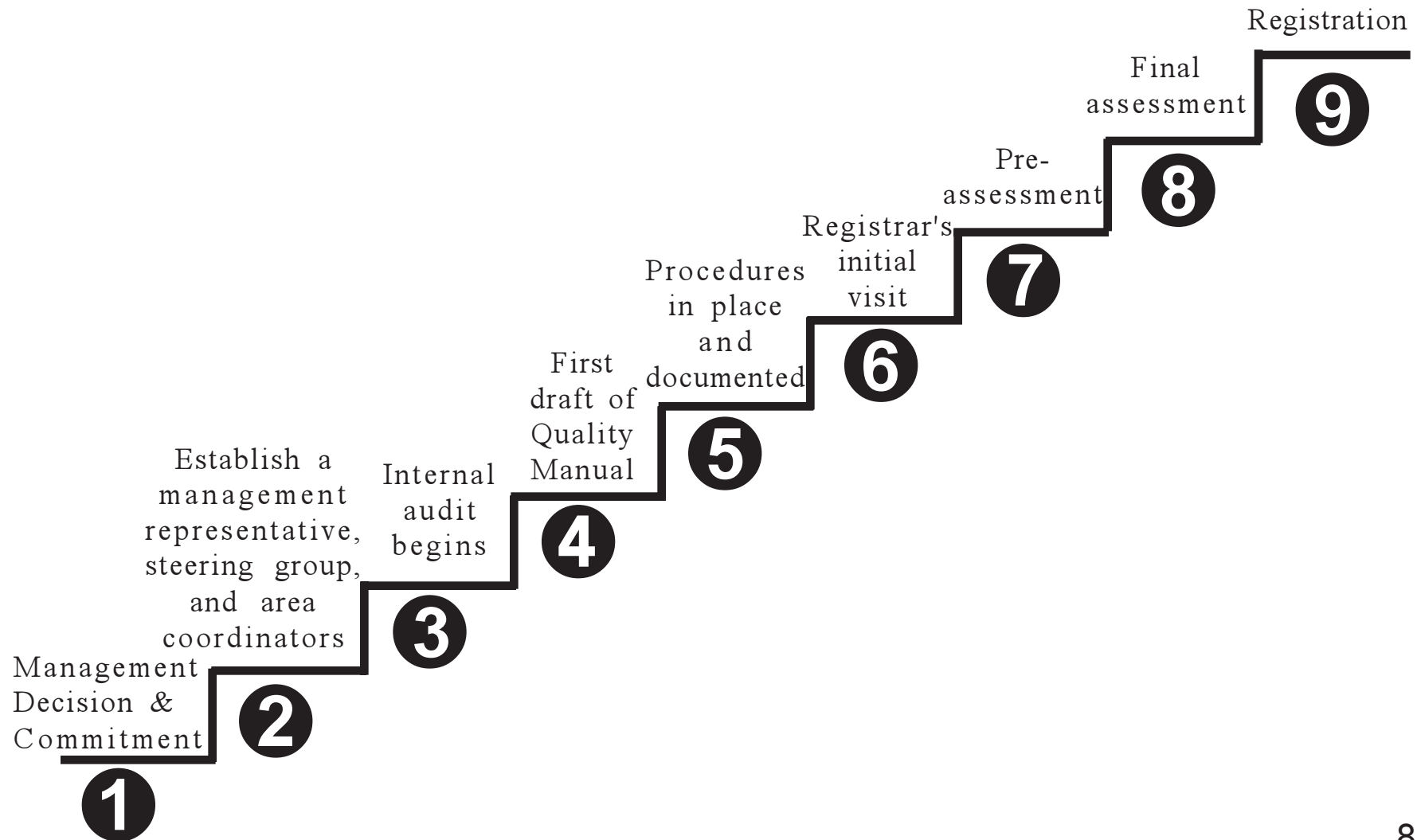
Forms & Records

Supports data input
and retention



7

What is the path to registration ?



DYNAMIC INSTRUMENTS, INC.

San Diego, CA

Time Line - Steps to Certification



- 1 Education at management level.
- 2 Communicate to entire organization; define audit teams.
- 3 Adequacy Audit #1; Compliance Audit #1;
Define areas for upgrading and improvement;
Set-up documentation teams.
- 4 Upgrade procedures; circulate and approve; provide training for upgraded procedures; implement upgraded procedures.
- 5 Repeat steps 1 thru 4
- 6 Revise Quality Manual; perform Adequacy Audit #2;
take corrective actions; perform Management Review #1;
approve Quality Manual; make upgrades to manual.
- 7 Correct deficiencies; perform Management Review #2.
- 8 Correct deficiencies.
- 9 Continuous improvement; resubmit to registrar.

What is Third Party Registration?

The registration of a Quality System by a third party to certify that the quality system, as documented and implemented, satisfies the requirements of the appropriate ISO 9000 standard.



A listing of Third Party Registrars is available on the Internet (over 30 companies available).

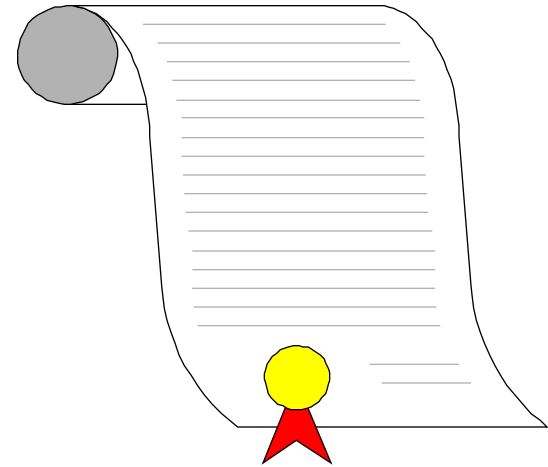
10

What is proof of ISO 9000 Certification?

Certificate of Registration

Identifies the:

ISO standard
company and address
date of issue
registration number



DO NOT DISPLAY

SHOW DYNAMIC INSTRUMENTS

CERTIFICATE OF REGISTRATION

12

ISO 9000 tidbits of interest

- As of August 27, 1993, there were approximately 1,000 US companies with ISO certification.
- Today - January 21, 1997 - there are over 10,000 companies in the US with ISO certification.
- Many foreign companies and governments require ISO 9000 certification and it is specified on their purchase orders or contracts.
- After certification, revisits by the certification company will be once a year - depending on the size of your product line.

Costs of Certification

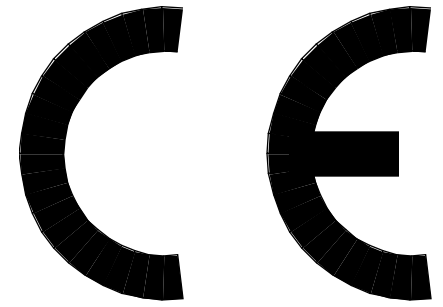
The costs stated below are the actuals from Dynamic Instrument's experience.



Upgrading MIL-Q-9858 System to ISO 9001	\$ 12,000
Special training for managers	40 hrs
(ten 4 hour sessions plus homework)	x qty trained
	x hourly rate
Initial Registrar's Fee	\$ 12,000
Recurring Annual Maintenance Fee	\$ 6,000 year
(plus travel and lodging)	
Handbook (used by Edward Demming & Mary Walton) Putnam Publishing Group 200 Madison Avenue New York, NY 10016	Provided by Registrar with Program

CE Mark

(European Community)



- The CE MARK is similar to the UL label
- Certain industries in Europe require ISO 9000 certification before a company can request usage of the CE mark. These are the health, safety, and RF communications equipment industries.
- UL does not require ISO 9000, but pressure is being applied to include ISO certification like the CE mark.

Summary and Conclusions

- Exported products will soon demand having ISO 9000 certification.
- Third party certification companies issue certificates that can be submitted with proposals and used for promotional purposes in marketing and sales.
- Revisits once a year by a third party certification company assist your organization in staying current with the latest ISO requirements.

