

**Remarks on  
ISO  
9001:2000**

**ISO 9001:2000  
for Software  
and Systems  
Providers**

*An Engineering Approach*

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# About SSQC

- Software Systems Quality Consulting
- Located in San Jose
- Since 1990, assisting organizations to develop and improve their engineering, manufacturing, and management practices
  - CMMI/CMM
  - ISO 9001:2000
  - Software QA and Testing
  - Business Process Reengineering and Benchmarking
  - Education and Training
- Members of the US TAG for ISO/IEC JTC1 SC7
- Authors **ISO 9001:2000 for Software and Systems Providers**
- SEI Partner Network
- Lead appraiser (CMM CBA-IPI, CMMI SCAMPI)

# Agenda

- Background
- Conclusions about ISO 9001:2000
- From the book
  - Architecture
  - Principles
  - Implementation roadmap
- A question of scope

# In our opinion, ISO 9001:2000 is

- A significant advance in the evolution of the ISO 9000 family of standards
  - Foundation for other standards
  - Significant benefits for Engineering community as the basis for improvement and integration
- At risk from the focus on registration process

# Particular areas of improvement

- Increased focus on coordinated process
  - Decreased focus on “documented procedures”
- Measurement and analysis
  - Of customer satisfaction
  - Of processes and product
  - Analysis of collected data on process

# Coordination

- New life for the quality manual
  - Scope
  - Procedures – identify: contains or references
  - Description of process sequence and interactions

# Explicit support for inter-group coordination and process integration

In addition to 5.5.3 Internal communication ISO 9001:2000 specifies:

## 7.2.1 Determination of requirements related to the product

The organization shall determine (a) ... requirements for delivery and post-delivery activities

## 7.3.3 Design and/or development outputs

Design and/or development output shall ...  
(b) provide appropriate information for purchasing, production and for service provision



# A realistic context for documentation

- 4.2.3 *For document control*
- 4.2.4 *For quality records*
- 8.2.2 *For internal audits*
- 8.3 *For control of nonconforming product*
- 8.5.2 *For corrective action*
- 8.5.3 *For preventive action* →
- and
- 4.2.1 d) Documents needed by the organization to ensure the effective planning, operation, and control of its processes

## Changes in registrars' auditors' behavior

- Audit processes
- Deal with greater variation due to less prescriptive language
- Understand what is in place and determine whether results are being achieved - not just look at the piles of required documentation
- ~Consulting
  - On-site training now permitted

# Measurement of customer satisfaction

8.2.1 Customer satisfaction ... the organization shall monitor information relating to customer perception ...

8.4 The analysis of data shall provide information relating to  
a) customer satisfaction ...

# Measurements extended to processes and product

## 5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those ... for product ... established at relevant functions and levels within the organization. .... The quality objectives shall be measurable and consistent with the quality policy.

## 5.6.2 Review input

Inputs to management review shall include ...  
(c) process performance and product conformity

## 8.2.1 Customer satisfaction

As one of the measurements of performance ..., the organization shall monitor ... customer perception ...

# Measurements extended to processes and product (cont.)

## 8.2.3 Monitoring and measurement of processes

... demonstrate the ability of processes to achieve planned results ... corrective action

## 8.2.4 Monitoring and measurement of product

- ... verify that product requirements are fulfilled
- ... carried out at appropriate stages of product realization
- Evidence of conformity with the acceptance criteria ... maintained
- Product release and delivery shall not proceed ...

# Analysis of collected data on the performance of the quality management system

## 8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information on:

- a) customer satisfaction (see 8.2.1),
- b) conformance to product requirements (see 7.2.1),
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

# The book

- To fill a gap
  - Engineering perspective
- Wider dissemination of a proven approach
  - Based on years of training courses
  - Enhance the value and impact of the standard
  - Improve rate of success
  - Facilitate and encourage reading the standard
  - Investment

# The architecture and content

## I. A Brief Orientation

1. Implementation roadmap
2. Terminology and definitions

## II. Paragraph-by-paragraph analysis

## III. Appendices

- A. History
- B. Rules for claiming conformity
- C. Compliance with 4.1
- D. Template for procedures
- E. A case study
- F. Implementation as a managed process
- G. Mapping the standard to core competencies
- H. Questionnaire for registrar selection

- Summary
- Implementation considerations
  - Related paragraphs
  - Examples

# The principles

1. ISO 9001:2000 is a requirements specification
  - WHAT, not HOW
2. It is easier to achieve compliance than to maintain it
3. Manage the implementation as if it were product development

# ISO Implementation Life Cycle

IMPLEMENT

MANAGE

COMMUNICATE

1. IDENTIFY  
PROCESSES NEEDED

2. DETERMINE  
INTERACTIONS

3. DETERMINE  
SEQUENCE

4. MAP THE  
STANDARD

5. MEASURE

# STEP 1

Identify the processes needed

[4.1(a)]

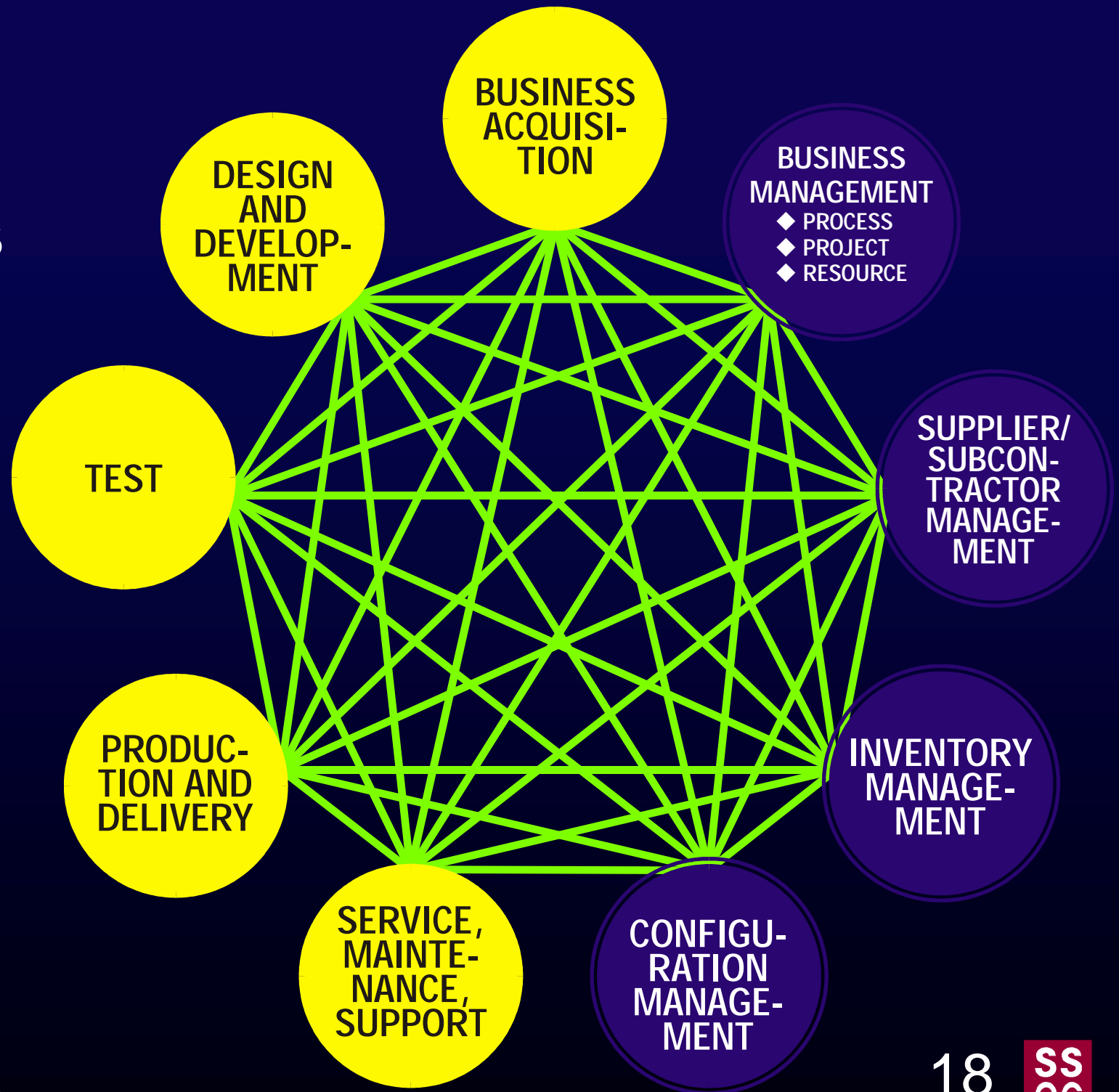
The value creation stream



# STEP 2

## Determine interactions

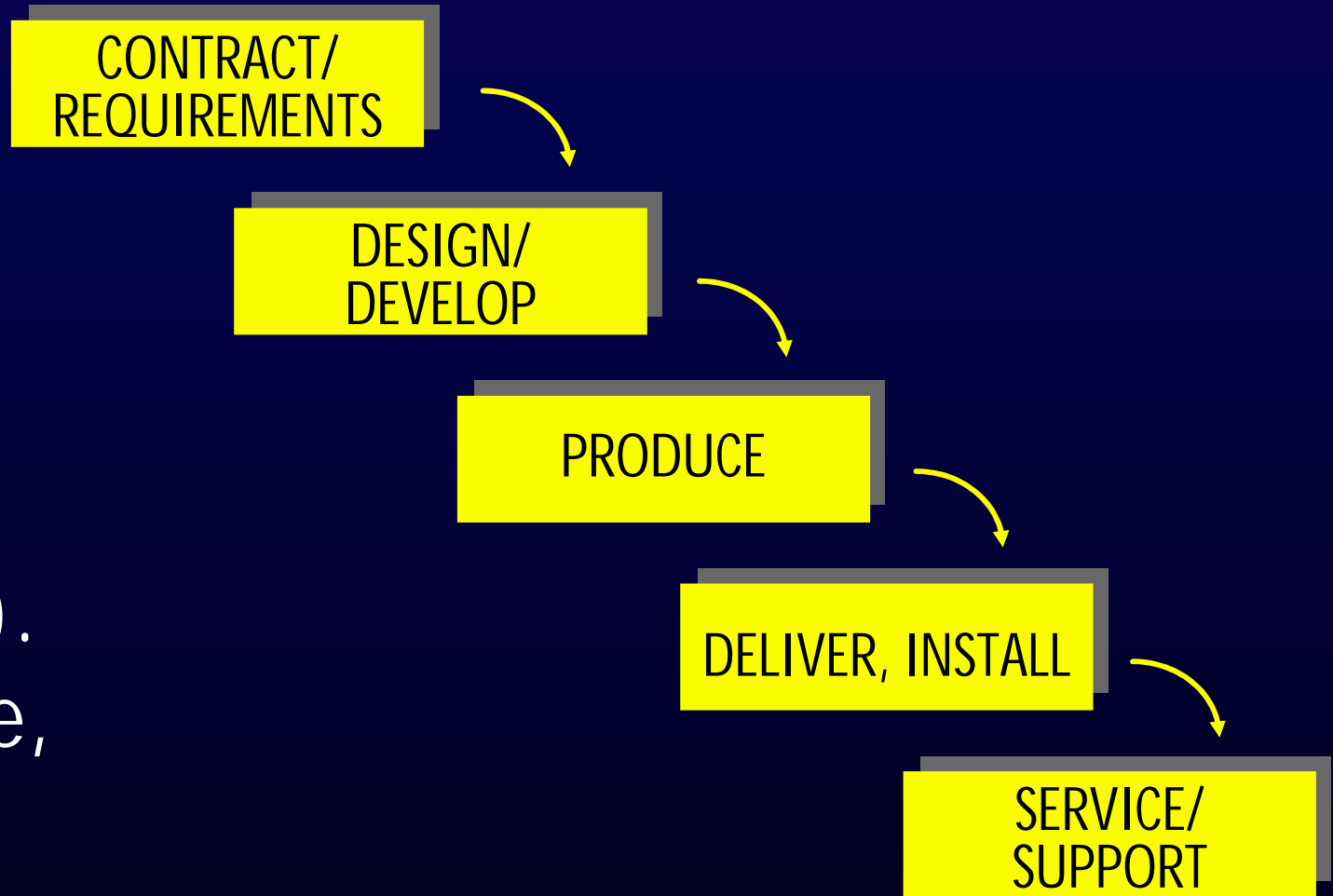
[4.1(b)]



# STEP 3

## Determine sequence [4.1(b)]

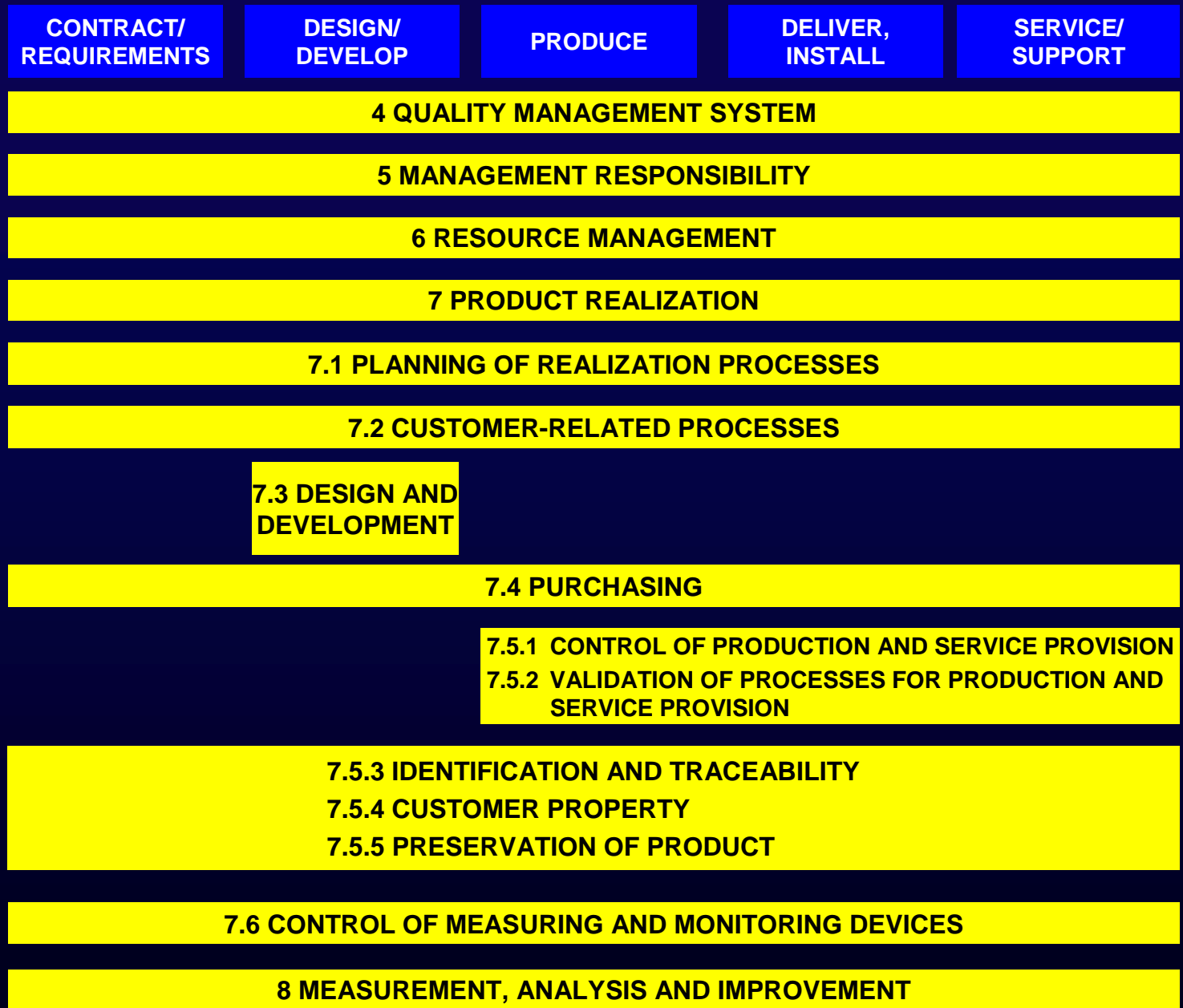
Define and  
implement  
product  
life cycle(s).  
For example,



# STEP 4

Map the requirements of the standard to the defined life cycle

Coverage analysis



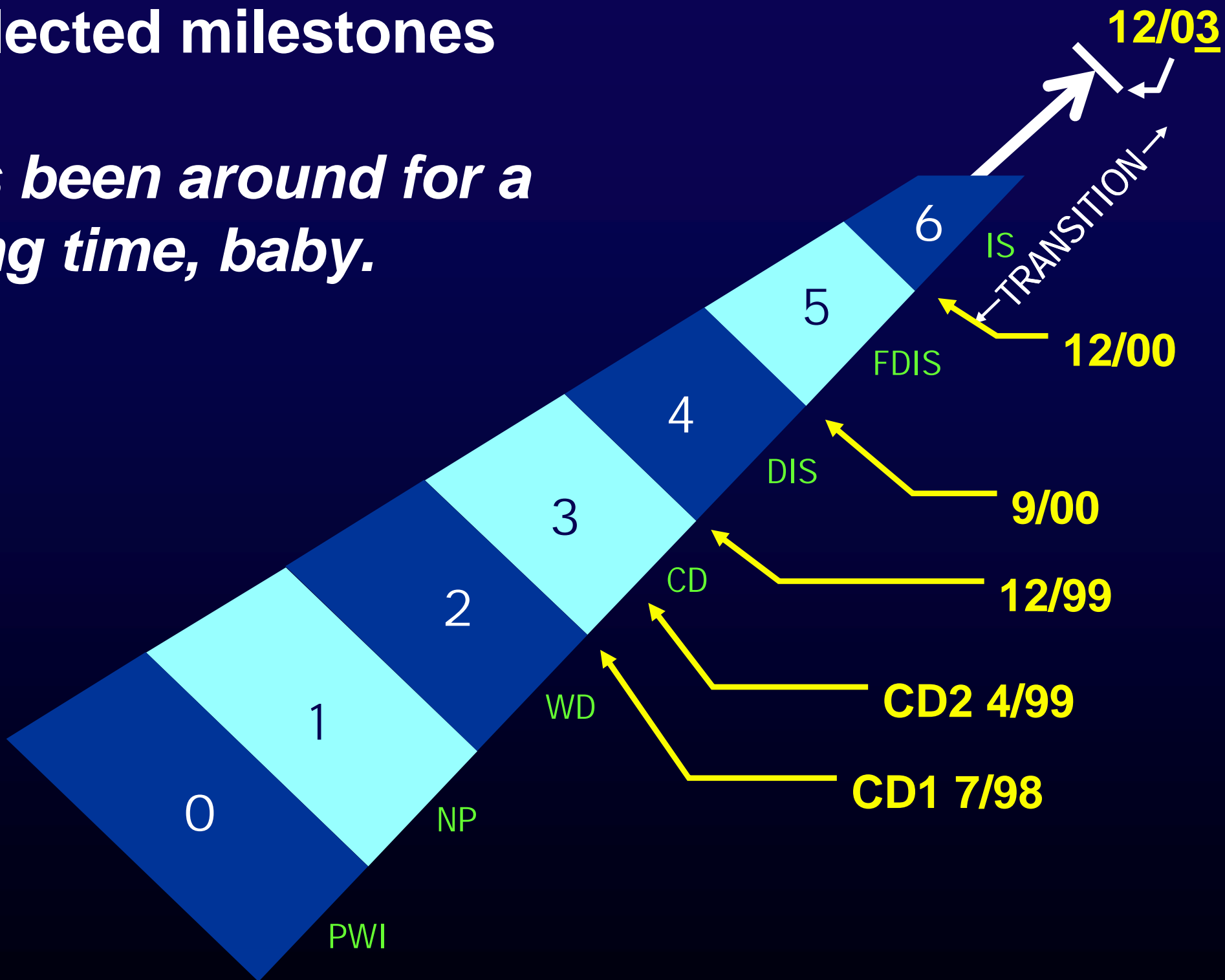
# Scope

- If Engineering is part of the organization, registrars are requiring that it be included in the scope of the registration - no more “9002”
  - ① It’s a good idea to develop integrated processes - that span the entire product life cycle - a “systems approach”
  - ② For many products and markets, there is little market value in paying to have Engineering assessed by the registrar

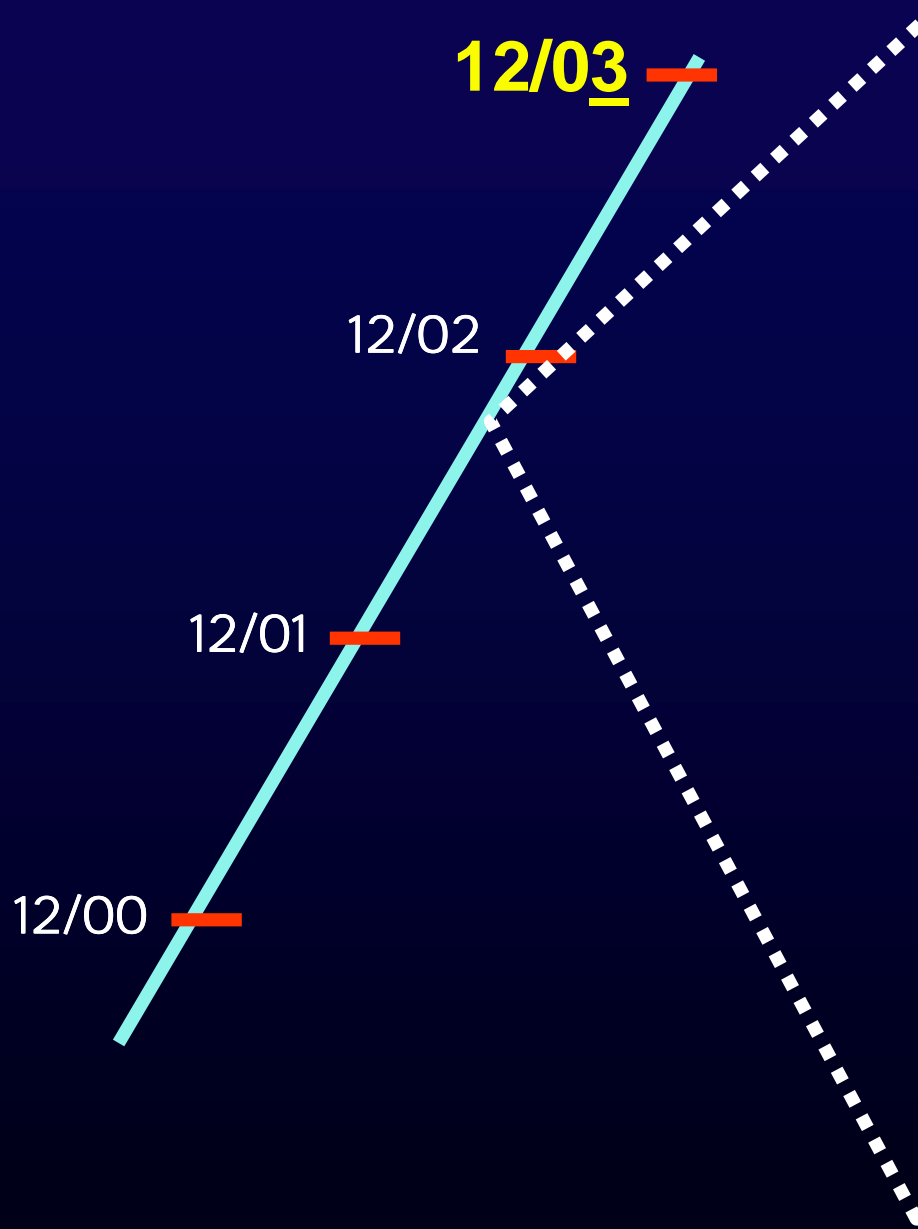
# Selected milestones

or

*It's been around for a long time, baby.*



# Reports about progress - in North America



Of 51,000 registered firms:

- 17% already registered to ISO 9001:2000 (or 3% or 10%)
- 73% plan to convert from 1994 to 2000 version
  - 40K to 50K companies
  - Typically 3 - 6 months
- 10% will allow registration to lapse

Of registrars:

- ~ 80 registrars
- 9 registrars hold 27,000 registrations

# A December miracle

## Countdown to ISO 9001:2000 Transition\*

**Deadline: Dec. 14, 2003**

**Days Remaining (as of Sept. 1): 105**

**Total ISO 9000 Series Registrations**

**ISO 9001:2000 Registrations**

**Percentage of ISO 9001:2000 Registrations**

**United States**

**42,328**

**11,074**

**26.2%**

**Canada**

**13,263**

**3,840**

**29.0%**

**Mexico**

**2,176**

**493**

**22.7%**

**North America**

**57,767**

**15,407**

**26.7%**

*As of August 14, 2003. Source: ISO 9001 Registered Company Database, available on-line at [www.qualitydigest.com](http://www.qualitydigest.com)*

# Questions?

# Contact Information

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