ISO 9001 & AS9100
Benefits of the Standards and Challenges of the Changes

Presented By

John Graham

to

AIAC *PACIFIC*

Presentation Outline
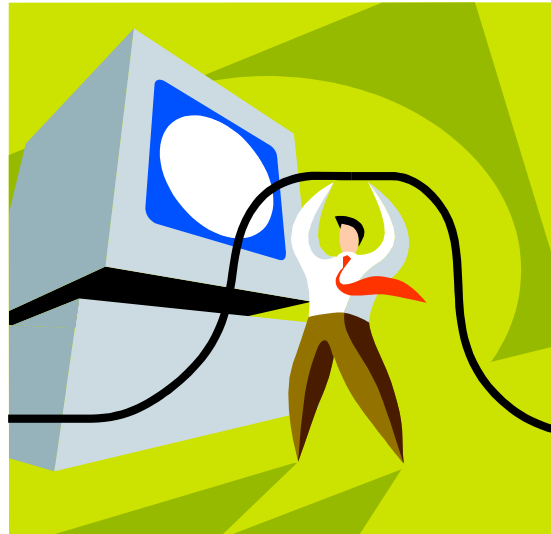
- Summary of Changes
- Transition Schedule
- Benefits of Certification
- How to Prepare for the Audit

The Changes

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ISO 9001 Reason for Change

- Enhance the company's ability to satisfy its customers

- Address the increasingly complex environments in which companies operate

- Better address the needs of all interested parties

- Provide a consistent foundation for the future

- Integrate with other management systems

AS9100 Reason For Change

- Maintain alignment with ISO 9001:2015 requirements

- Include Aviation, Space and Defense stakeholders' needs identified since the last revision

- Address needed clarifications identified by IAQG experience since the last revision

Key Changes

- High Level Structure (HLS) & Terminology

- Risk-based thinking

- Process approach reinforced with integration of the QMS into organization's business processes

- Increased emphasis on management of changes

- Introduction of knowledge management

- Preventive action integrated throughout as risk identification and opportunities for improvement

Key Changes

- Clearer understanding of the purpose and scope of the organization

- Alignment of QMS policy and objectives with the strategy of the organization

- Increased performance evaluation requirements

- Greater flexibility with documentation

- More compatible with services

AS9100 Table of Contents

AS9100C

1 Scope

2 Normative Reference

3 Terms and Definitions

4 Quality Management System

5 Management Responsibility

6 Resource Management

7 Product Realization

8 Measurement, Analysis and Improvement

AS9100D

1 Scope

2 Normative Reference

3 Terms and Definitions

4 Context of the Organization

5 Leadership

6 Planning

7 Support

8 Operation

9 Performance Evaluation

10 Improvement

PDCA Quality Management Model

Context of Organization (4)

Context of Organization (4)

Customer Requirements

Customer Satisfaction

Plan

Support (7) Operation (8)

Do

Planning (6)

Leadership (5)

Performance Evaluation (9)

Act

Improvement (10)

Check

The High Level Structure

Plan				**Do**	**Check**	**Act**
4 **Context of organization**	**5** **Leadership**	**6** **Planning**	**7** **Support**	**8** **Operation**	**9** **Performance Evaluation**	**10** **Improvement**
4.1 Understanding context	**5.1** Leadership and commitment	**6.1** Actions to address risk and opportunity	**7.1** Resources	**8.1** Operational planning & control	**9.1** Monitoring, measurement, analysis and evaluation	**10.1** General
4.2 Interested parties	**5.2** Policy		**7.2** Competence	**8.2** Requirements for products & services		**10.2** Nonconformity and corrective action
4.3 Scope	**5.3** Organizational roles, responsibilities and authorities	**6.2** Objectives and planning	**7.3** Awareness	**8.3** Design and Development of products & services	**9.2** Internal audit	**10.3** Continual improvement
4.4 Processes		**6.3** Planning of changes	**7.4** Communication	**8.4** Control of externally provided processes, products	**9.3** Management review	
			7.5 Documented information	**8.5** Production and service provision		
				8.6 Release of products & services		
				8.7 Control of NC outputs		

Key Definitions

context of the organization

combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives

interested party

(stakeholder)

person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

external provider

(external supplier)

provider that is not part of the organization

Source: ISO 9000:2015

Key Definitions

human factor

characteristic of a person having an impact on an object under consideration

documented information

information required to be controlled and maintained by an organization and the medium on which it is contained

Source: ISO 9000:2015

Terminology Changes

2009 Term   **>**   **2016 Term**

Products **>** Products and services

Management Representative **>** Top Management

Work environment **>** Environment for the operation of processes

Monitoring & measuring equipment **>** Monitoring & measuring resources

Exclusions **>** Not used

Purchased product **>** Externally provided products and services

Supplier **>** External provider

Documentation
Quality manual
Documented procedures
Records
] **>** Documented information

Documented Information

Some documented information must be "maintained"
and

other documented information must be "retained"

There are 8 requirements to "maintain documented information"

There are 24 requirements to "retain documented information"

There are no requirements for creating "Documented Procedures"

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Summary of Requirements

453 total requirements in AS9100D

118 are completely new

54 have additional requirements included

306 are ISO requirements

147 are AS requirements

47 are partially or completely new

Transition Schedule

Target Dates	Activities
August 2016	• Publication of Supplemental Rule (SR003) Draft Version.
September 2016	• 9100 QMS standard approved for publication in all sectors.
October 2016	• 9101 QMS Audit standard, 9110 Maintenance QMS, and 9120 Distributor QMS published.
November 2016	• Mandated Aerospace Auditor "transition" training for 9100 and 9101 available in IAQG languages.
December 2016	• OASIS Next Generation project phase 1 complete. Database available for entry of transition audit results.
December 1, 2016	• Certification Bodies 9100:2016 readiness communicated to Accreditation Body • Certification Bodies provide documentation to certified organizations regarding transition requirements and transition process.
January 2017	• Mandated Aerospace Auditor "transition" training for 9110 and 9120 modules available in IAQG languages.
March 1, 2017	• Certified organizations provide intention to transition to the 2016 revision to their Certification Bodies.
June 2017	• All future audits must be to the 9100/9110/9120:2016 standard using 9101:2016 audit process.
September 2018	• Transition complete all 9100/9110/9120:2009 certificates are no longer valid.

Source: IAQG Website
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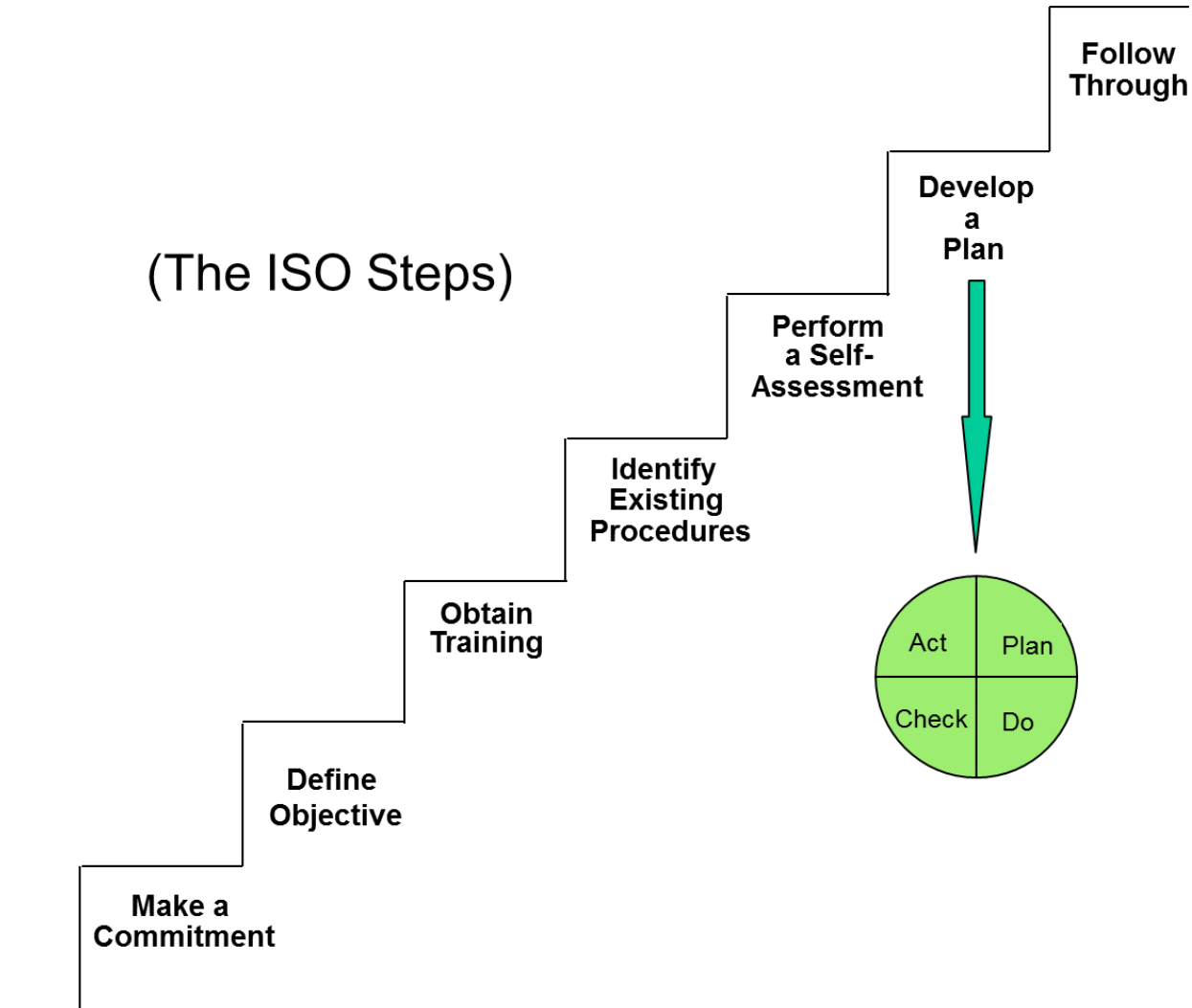# Achieving Certification Through Organizational Improvement
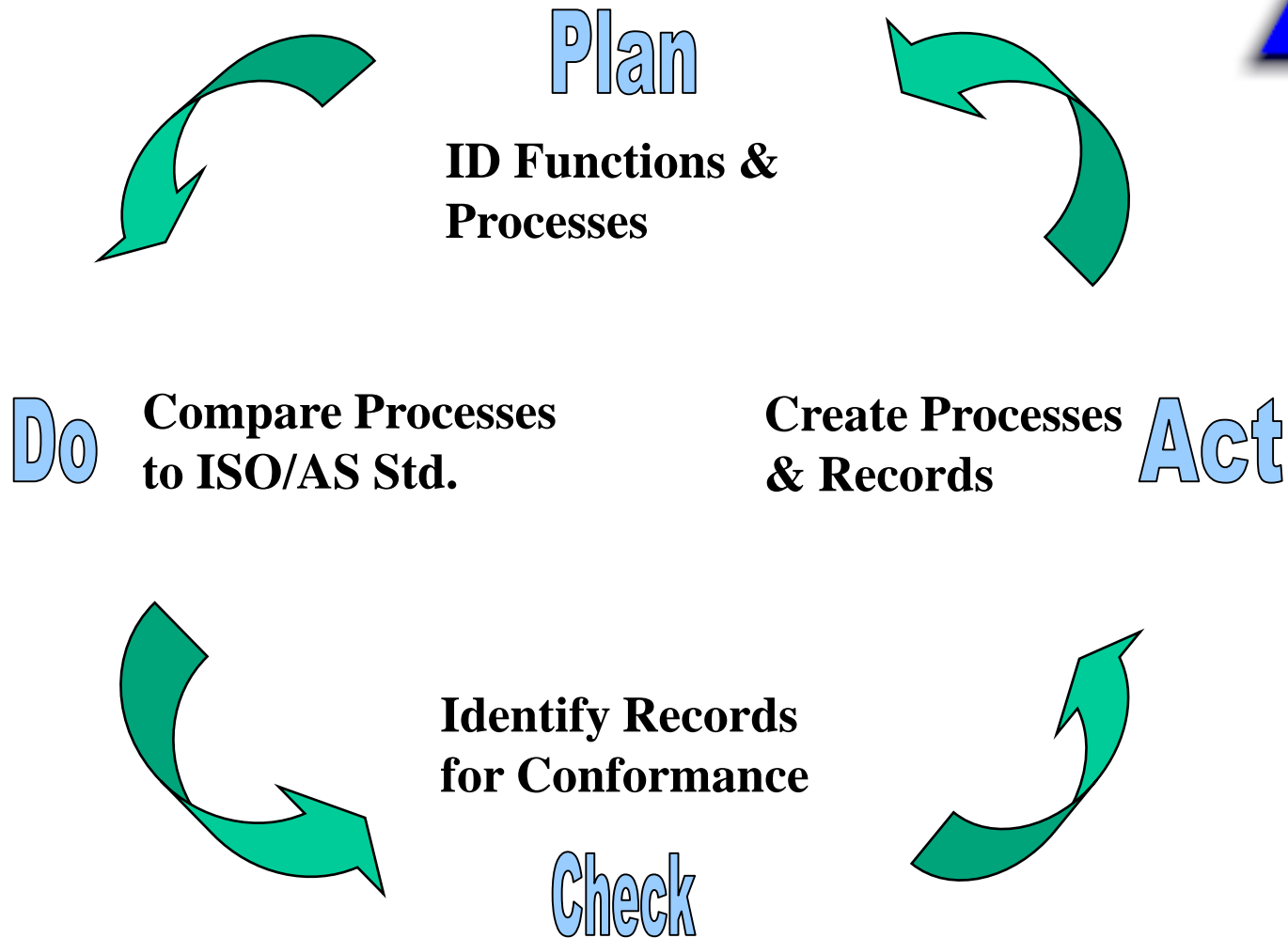
How to Become Certified

- Understand the advantages and disadvantages of certification

- Make a commitment

- Clearly define your objective

- Evaluate need for external support

- Create a project plan with clear goals and objectives

- Select a Certification Body

The Steps to Certification

(The ISO Steps)

Follow Through

Develop a Plan

Perform a Self-Assessment

Identify Existing Procedures

Obtain Training

Define Objective

Make a Commitment

Act | Plan

Check | Do

Process – Getting Started

Plan

ID Functions & Processes

Do Compare Processes to ISO/AS Std.

Act Create Processes & Records

Identify Records for Conformance

Check
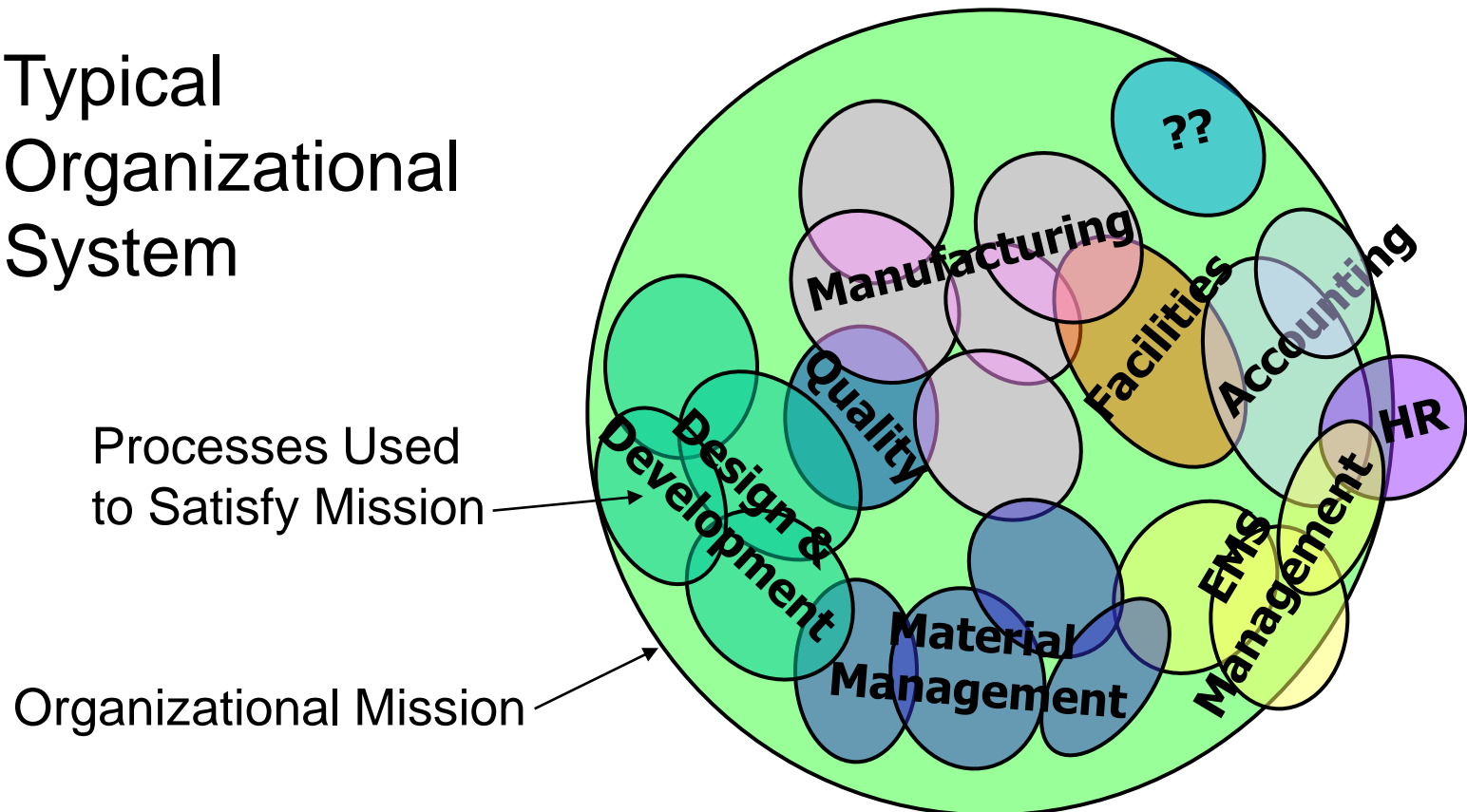
The Organizational Starting Point

What Organizational Evolution Creates

Typical Organizational System

Processes Used to Satisfy Mission

Organizational Mission

Manufacturing
??
Facilities
Accounting
Quality
Design & Development
HR
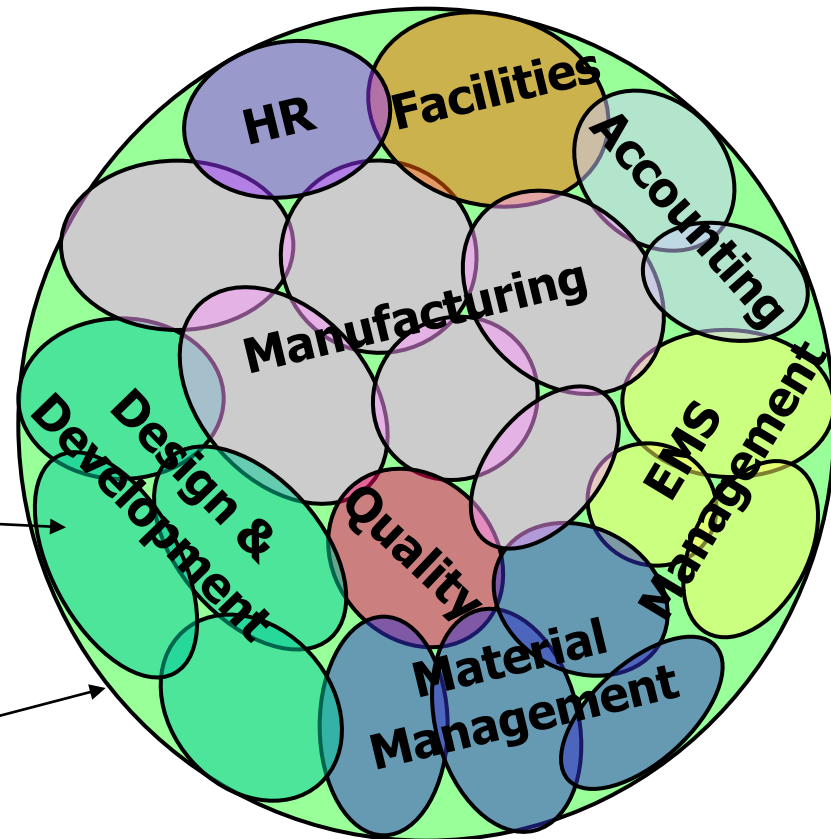Material Management
EMS Management

Process Improvement Results

What We Can Achieve With
Good Process Planning

Optimized
Organizational
System

Processes Used
to Satisfy Mission

Organizational Mission

HR

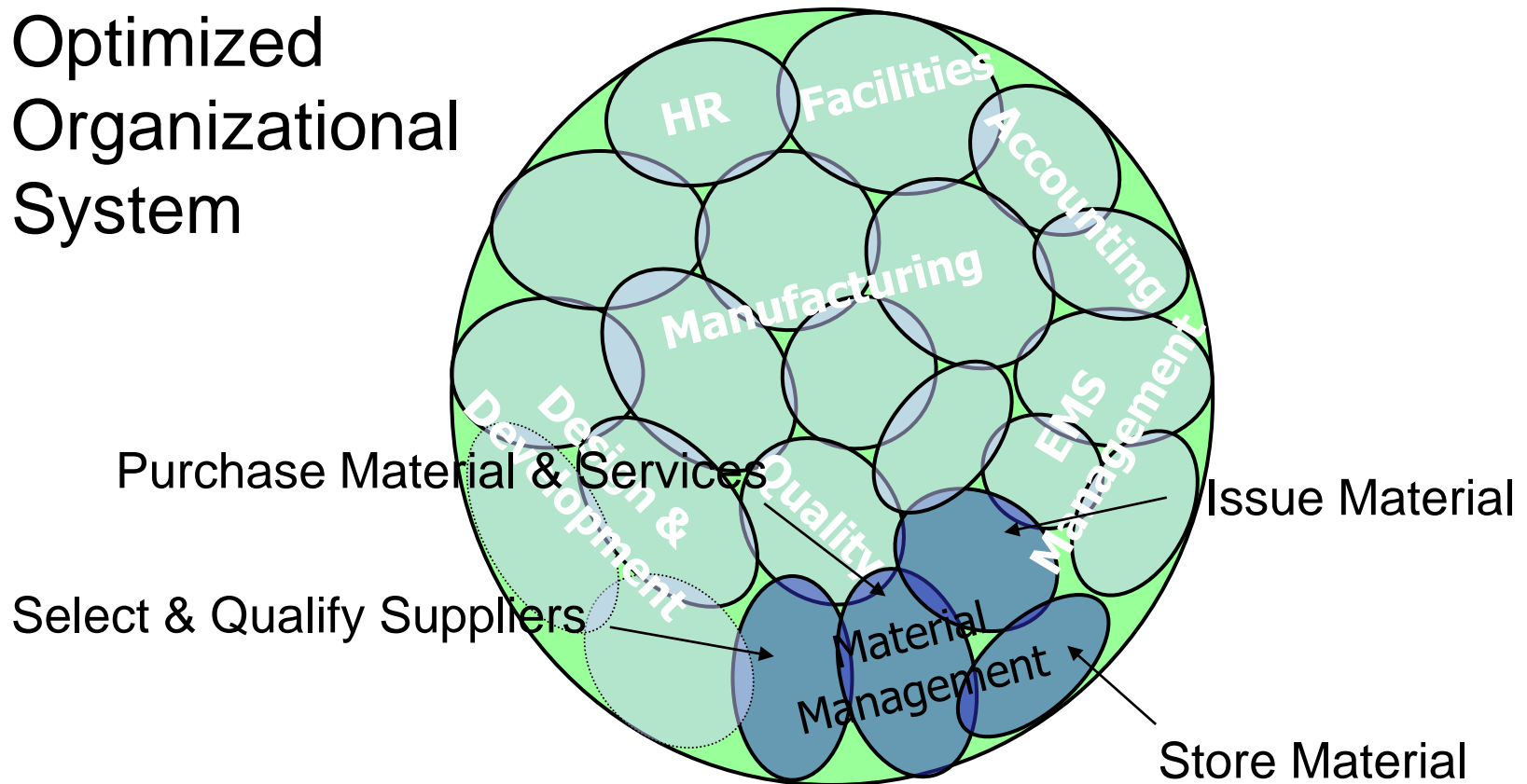Facilities

Accounting

Manufacturing

EMS Management

Design & Development

Quality

Material Management

Business Process Mapping Results

Clearly Define Process Interface

Optimized Organizational System

Purchase Material & Services

Select & Qualify Suppliers

Issue Material

Store Material

HR Facilities Accounting Manufacturing Design & Development Quality EMS Management Material Management

Typical Manufacturing Business Processes

Develop & Update Business Plan

Establish & Maintain Contracts

Administer Order Entry

Plan, Monitor, & Expedite Production

Select, Qualify, & Monitor Suppliers

Purchase Materials & Services

Receive & Verify Materials

Handle, Store & Issue Materials

Manage Nonconforming Product & Materials

Manufacture Products

Conduct First Article Inspection

Identify & Package Products

Develop & Control Documents & Data

Control QMS Data

Typical Manufacturing Business Processes

Define & Manage Communication System

Control Monitoring & Measuring Equipment

Maintain Facilities & Equipment

Control Tools & Software

Develop & Train Employees

Administer Human Resources

Conduct QMS Audits

Perform Corrective & Preventive Action

Review & Update BMS

Establish Monitoring & Measuring Controls

Plan & Manage Projects

Prepare & Ship Products

Coordinate Customer Service

Certification

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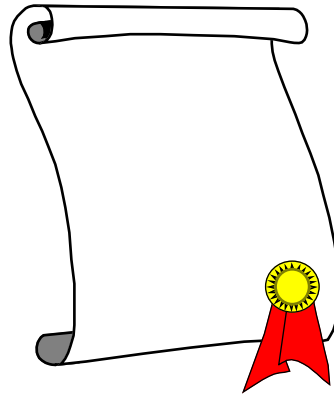
Benefits of Certification

- Approval to sell products to customers requiring certification

- Approval to sell to Aerospace OEMs

- Can result in significant improvement of your business processes

- Required annual audits will help maintain ongoing conformance

Current Issued Certificates

1.2 Million ISO 9001 Certificates
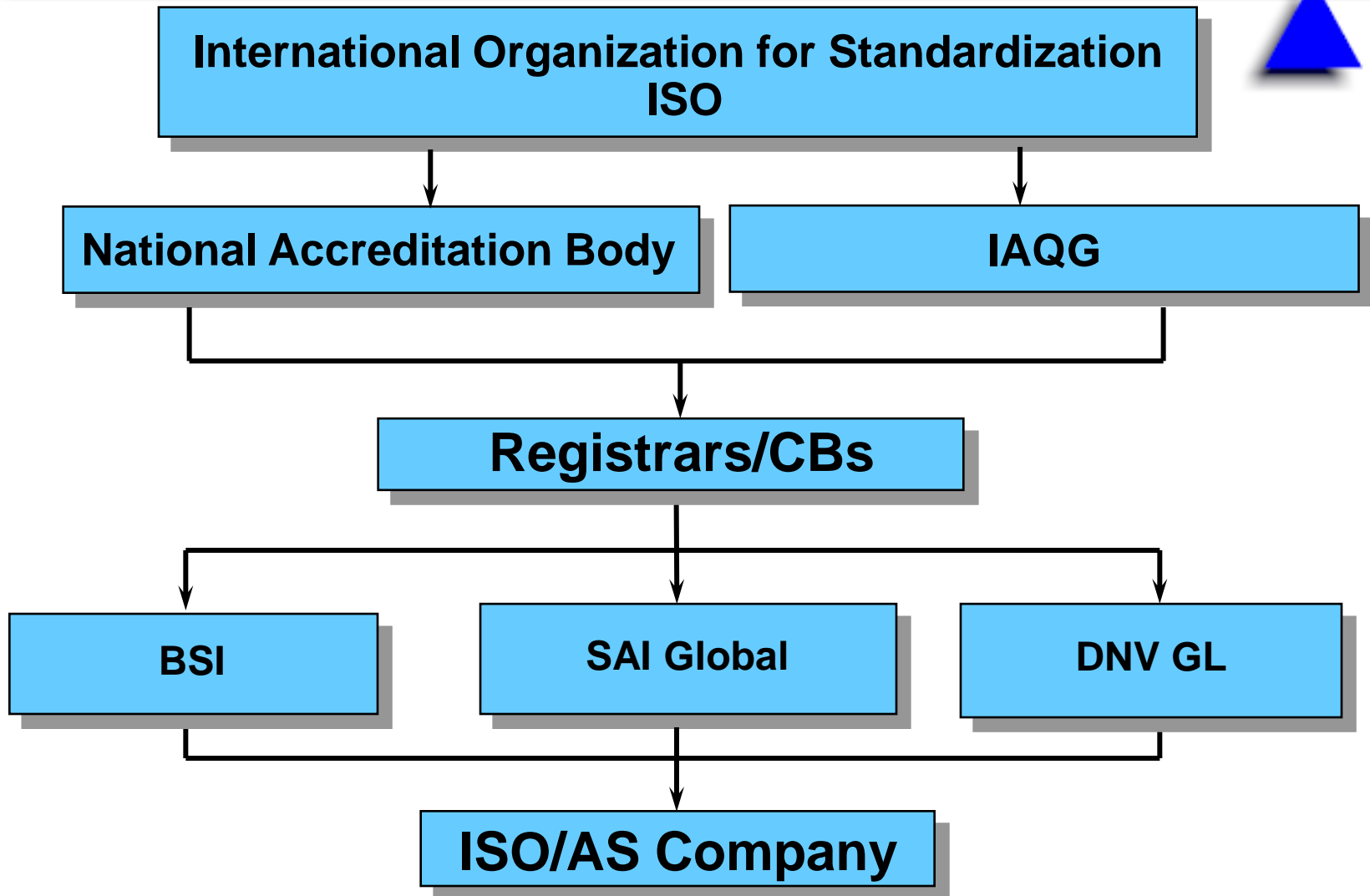
18,000 AS9100 Certificates

Selecting a Registrar

What is Registration?

The audit and approval of a quality management system against the ISO 9001/AS9100 standard by an independent third party registrar
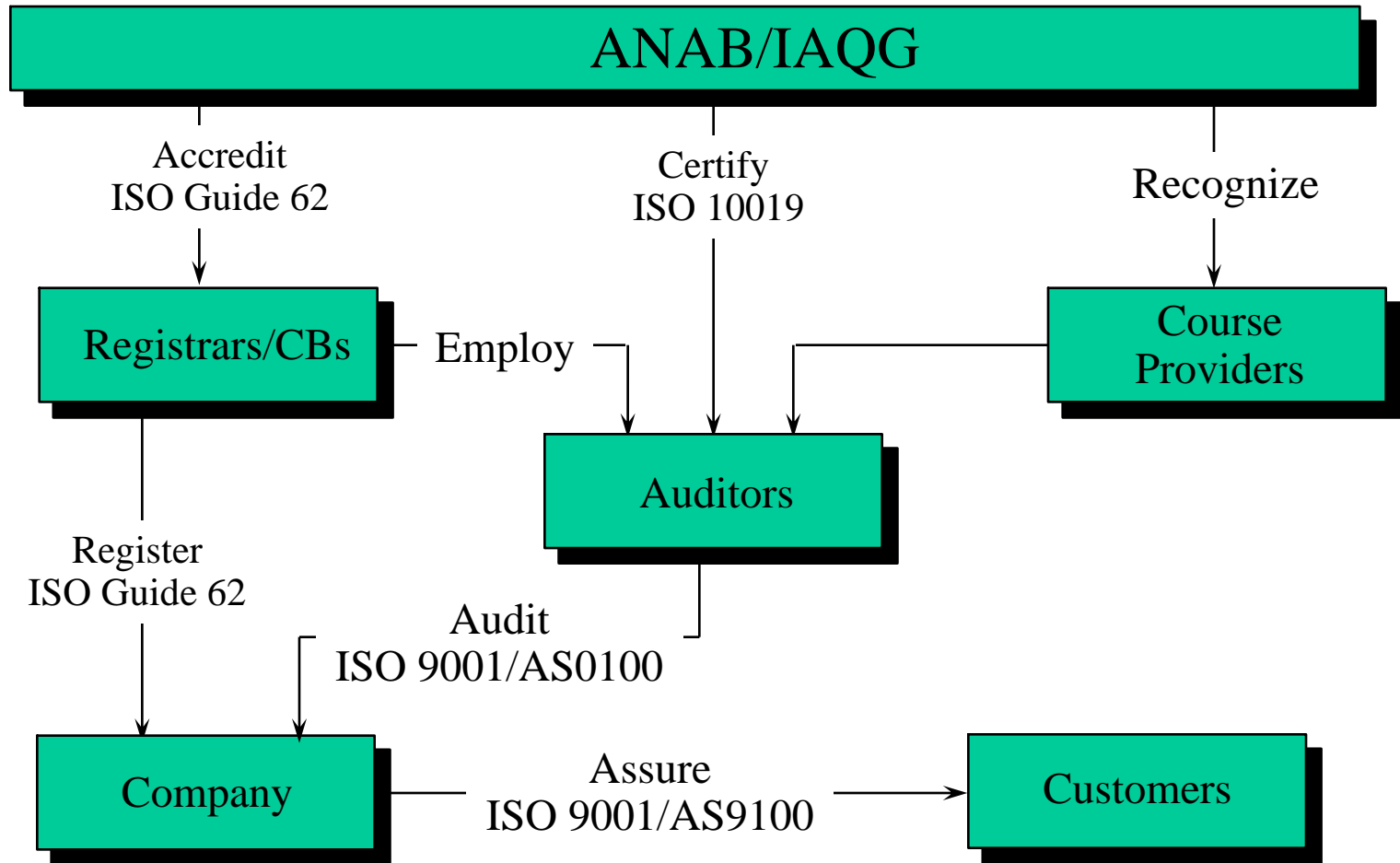
What is a Registrar/CB?

An accredited organization (a Certification Body) providing ISO/AS quality management system assessment services

Certification System

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│  International Organization for Standardization       │
│                      ISO                              │
└─────────────────────────────────────────────────────┘
          │                              │
          ▼                              ▼
┌──────────────────────────┐   ┌──────────────────────┐
│ National Accreditation    │   │        IAQG          │
│        Body               │   │                      │
└──────────────────────────┘   └──────────────────────┘
          │                              │
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                         ▼
              ┌────────────────────┐
              │   Registrars/CBs   │
              └────────────────────┘
                         │
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      ▼                  ▼                  ▼
┌──────────┐    ┌──────────────┐    ┌──────────────┐
│   BSI    │    │  SAI Global  │    │   DNV GL     │
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              ┌────────────────────┐
              │  ISO/AS Company    │
              └────────────────────┘
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National Accreditation Program

Information Source

Reference Web Sites

– IAQG Deployment Support Material

  http://www.sae.org/iaqg/organization/requirements.htm

– ISO TC/176/SC2 Home Page

  http://www.iso.org/iso/iso_technical_committee?commid=53896

– SAE International – AS9100

  http://www.sae.org/aerospace/

Thank You

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Changes

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