



TACKLING ISO 9000 DOCUMENTATION

Presented by

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PRESENTER PROFILE

- ◆ Team Leader, Document Management Group, AlliedSignal Aerospace Canada (ASACa), Toronto facility
- ◆ Internal Auditor for ISO 9001 at ASACa, Toronto
- ◆ Graduate of the ASQC 'Documenting ISO 9000' course
- ◆ Faculty Advisor, Humber College of Applied Arts & Technology Technical Manual Writing Certificate Course

PRESENTER PROFILE

- ◆ Faculty Advisor , Sheridan College of Applied Arts & Technology, ISO 9000 Specialist Course
- ◆ Instructor, Sheridan College of Applied Arts & Technology, ISO 9000 Documentation
- ◆ Author of *“Documenting ISO 9000: Guidelines for Compliant Documentation”*

WORKSHOP OBJECTIVES

- ◆ Introduce the ISO 9000 series of Quality Standards and their supporting guidelines
- ◆ Show how the Technical Communicator positively impacts the implementation of ISO 9000
- ◆ Detail the documentation requirements of ISO 9000
- ◆ Provide practical experience at writing ISO 9000 compliant documentation

WORKSHOP AGENDA



- ◆ An Introduction to ISO 9000
- ◆ BREAK
- ◆ Technical Communicators and ISO 9000 Implementation
- ◆ A Documentation Strategy for ISO 9000
- ◆ Document Control within ISO 9000

WORKSHOP AGENDA



- ◆ LUNCH
- ◆ Documenting ISO 9000
- ◆ BREAK
- ◆ Writing ISO 9000 Documentation
- ◆ Summary



AN INTRODUCTION TO ISO 9000

WHO IS THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION?



- ◆ A global federation of the national standards bodies of over 90 countries
- ◆ Works to promote common standards and to define and 'harmonize' product, service, and business practices worldwide
- ◆ Canada is represented by the Standards Council of Canada (SCC) and the U.S. by the American National Standards Institute (ANSI)

ISO 9000 BACKGROUND

- ◆ Concept of quality system assessment was developed during WW II
- ◆ Standards that evolved were the precursor to the NATO AQAP series
- ◆ These were further developed by the British into the MoD 05 series

ISO 9000 BACKGROUND



- ◆ MIL-STD-9858A developed in the U.S
- ◆ Companies NOT dealing with the military developed a parallel standard, BS 5179 which became BS 5750 in 1979

ISO 9000 BACKGROUND



- ◆ Concepts of other national standards, such as the Canadian CSA's Z-299 and various U.S. military standards, were taken into consideration
- ◆ Consensus from the global community led to the ISO 9000 series of standards in 1987

ISO 9000 RATIONALE



- ◆ A response to the emerging globalization of markets
 - North American Free Trade Act (NAFTA)
 - European Free Trade Association (EFTA)
 - European Community (EC)
- ◆ Consistency in meeting customer requirements is now a measure of corporate efficiency

ISO 9000 RATIONALE



- ◆ Partnering arrangements with suppliers
- ◆ Presents an opportunity for internal improvement

THE ISO 9000 QUALITY SYSTEM

- ◆ What it IS
 - a way of life
 - defines Quality System requirements
 - aimed at preventing nonconformity at all stages, from design through to servicing.
 - systematic ‘process’ control of all activities affecting the quality of the product
 - satisfies company and customer needs

THE ISO 9000 QUALITY SYSTEM



- ◆ What it IS NOT
 - a ‘coffee table’ quality system
 - a cure for poor product design or manufacturing methods
 - a barrier to creativity or continuous improvement
 - an attempt to bury processes in paper
 - a ‘flavour of the month’ initiative

THE ISO 9000 SERIES OF STANDARDS

- ◆ Two Management Guidelines
 - ISO 9000-1 - Quality Management & Quality Assurance Standards - Guidelines for Selection & Use
 - ISO 9004-1 - Quality Management & Quality System Elements - Part 1: Guidelines for Management

ISO 9000 SERIES OF STANDARDS

- ◆ Three Quality Standards
 - ISO 9001 - Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing
 - ISO 9002 - Quality Systems - Model for Quality Assurance in Production, Installation, and Servicing
 - ISO 9003 - Quality Systems - Model for Quality Assurance in Final Inspections and Testing

ISO 9000 SERIES OF STANDARDS

- ◆ Additional Guidelines
 - ISO 9000-2 - Quality Management and Quality System Elements - Generic System Guidelines
 - ISO 9000-3 - Quality Management and Quality System Elements - Guidelines for Software
 - ISO 9000-4 - Quality Management and Quality System Elements - Guidelines for Program Management

ISO 9000 SERIES OF STANDARDS

- ◆ Additional Guidelines
 - ISO 9004-2 - Quality Management and Quality System Elements - Part 2: Guidelines for Services
 - ISO 9004-3 - Quality Management and Quality System Elements - Part 3: Guidelines for Processed Materials
 - ISO 9004-4 - Quality Management and Quality System Elements - Part 4: Guidelines for Quality Improvement

ISO 9000 SERIES OF STANDARDS

- ◆ Additional Guidelines
 - ISO 9004-5 - Quality Management and Quality System Elements - Part 5: Guidelines for Quality Plans
 - ISO 9004-6 - Quality Management and Quality System Elements - Part 6: Guidelines on Configuration Management
 - ISO 10013 - Guidelines for Developing Quality Manuals

OBJECTIVES OF ISO 9000

- ◆ Provides organizations with useful, internationally recognized models for operating a quality management system
- ◆ To have a Quality System in place which is third-party registered

OBJECTIVES OF ISO 9000

- ◆ To establish a compliance standard that is followed 24 hours-a-day, 7 days-a-week, 52 weeks-a-year
- ◆ To establish a standard that can be applied to ALL industry and business types

QUALITY SYSTEM TYPES



- ◆ Product-oriented Quality Systems
- ◆ Process-oriented Quality Systems

PRODUCT-ORIENTED QUALITY SYSTEMS



- ◆ Product-oriented Quality Systems are based on product inspections and are generally department-based

PROCESS-ORIENTED QUALITY SYSTEMS

- ◆ Process-oriented Quality Systems views the whole organization and its manufacturing system as an integrated unit

WHY REGISTER?

- ◆ Reported by 620 U.S. and Canadian registered companies
 - To meet customer requirements 27.4%
 - To institute a program of quality improvement 21.8%
 - To gain competitive advantage 15.6%
 - To comply with external regulatory forces 9.0%

EXTERNAL BENEFITS OF REGISTRATION



- ◆ Reported by 620 U.S. and Canadian registered companies
 - Higher perceived product quality 33.5%
 - Improved customer satisfaction 26.6%
 - Competitive advantage 21.5%
 - Reduced customer quality audits 8.5%

INTERNAL BENEFITS OF REGISTRATION

- ◆ Reported by 620 U.S. and Canadian registered companies
 - Better documentation 32.4%
 - Greater quality awareness 25.6%
 - Positive ‘cultural change’ 15.0%
 - Increased operational efficiency/
productivity 9.0%

COSTS vs SAVINGS

- ◆ Reported by 620 U.S. and Canadian registered companies
 - First year average realized savings \$179,000
 - Average costs associated with registration \$245,000
(incl. audit fees & internal expenses)
 - Time to prepare for first audit +1 year

ISO 9000 and TQM



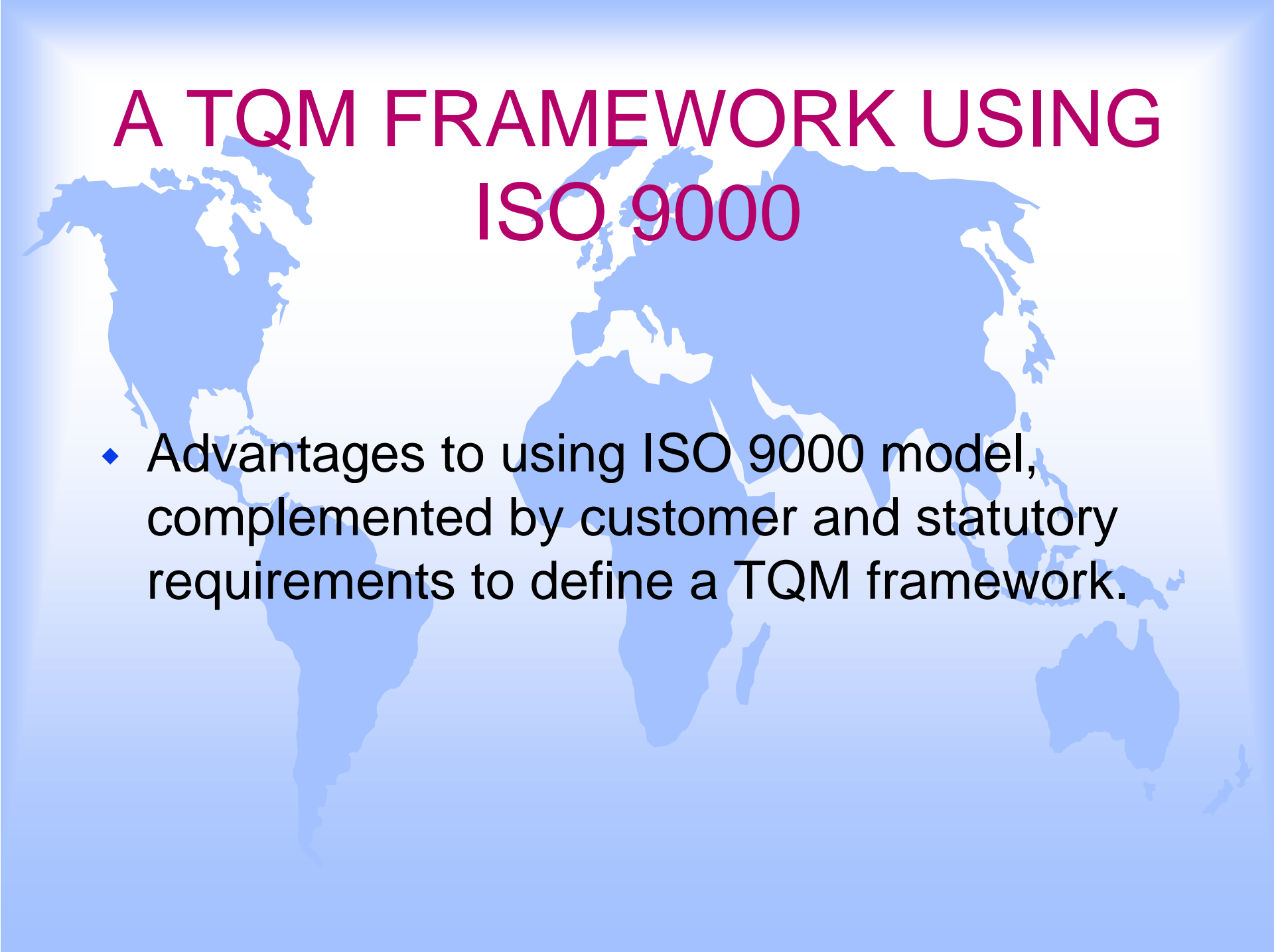
- ◆ What's holding us back?
- ◆ Why aren't TQM efforts working?
- ◆ Why haven't costs decreased?
- ◆ Why has productivity not increased?

TQM and ISO 9004



- ◆ Change 'should' to 'shall' in ISO 9004 and you will have a standard created for TQM.
- ◆ ISO 9004, taken as a whole, is a model of a management structure with an emphasis on quality.
 - the definition of TQM

A TQM FRAMEWORK USING ISO 9000



- ◆ Advantages to using ISO 9000 model, complemented by customer and statutory requirements to define a TQM framework.



HOW TO MAKE ISO 9000 IMPLEMENTATION DIFFICULT

- ◆ Keep your current documentation at all costs.
- ◆ Don't question the old way of doing things.



HOW TO MAKE ISO 9000 IMPLEMENTATION DIFFICULT

- ◆ Ignore contributions from people actually doing the job.
- ◆ Document everything to the smallest detail.



HOW TO MAKE ISO 9000 IMPLEMENTATION DIFFICULT

- ◆ Blindly throw employees and money at ISO 9000 implementation.
- ◆ Attempt implementing ISO 9000 requirements **WITHOUT** a plan.