TACKLING ISO 9000 DOCUMENTATION

Presented by

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PRESENTER PROFILE

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- 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 SERIES OF STANDARDS

- Three Quality Standards
  - 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 9000-3 - 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 9004-3 - 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
Additional Guidelines

- 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 are based on product inspections and are generally department-based.
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 hasn’t 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
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.