

# AUDITING THE NEW MSS

CONFORMITY VERSUS PERFORMANCE

By: JP Russell  
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JP Russell

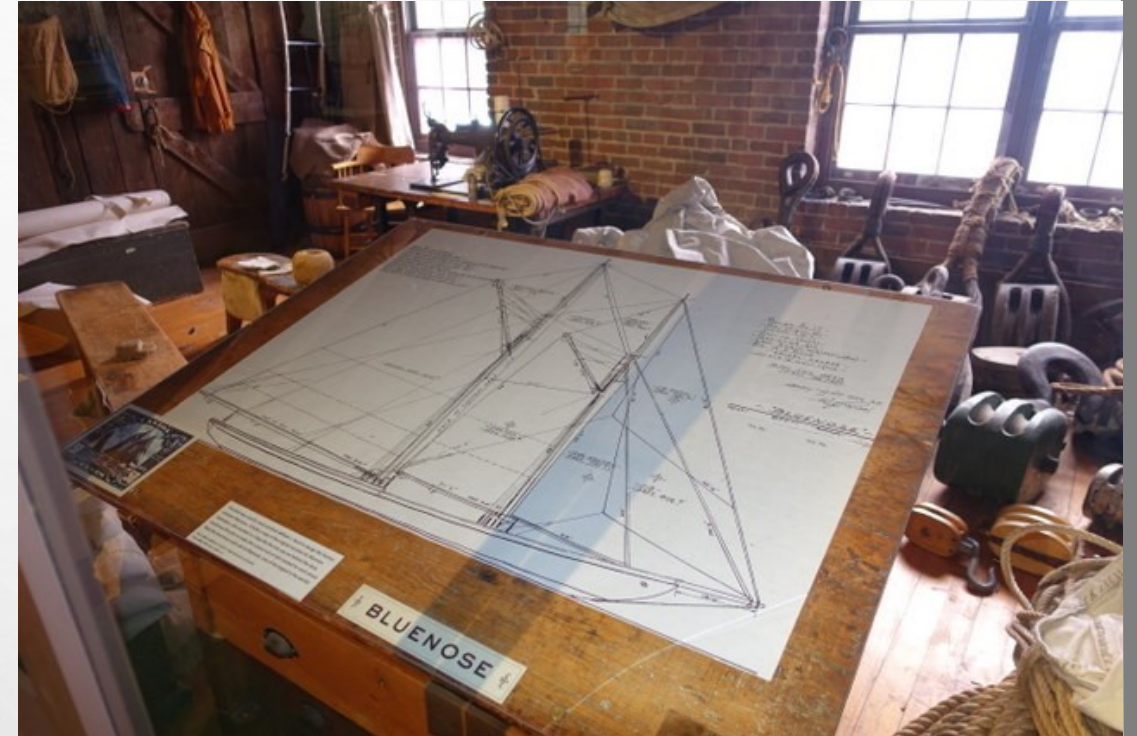
- Author of several books about quality, auditing & standards
- Editor of The ASQ Auditing Handbook , 1<sup>st</sup>-4<sup>th</sup> editions
- Columnist for Quality Progress Magazine for 15 years
- Member of US TAG TC 176 (ISO 9000 series)
- Member of US TAG 302 – Auditing ISO 19011
- Secretary for ASQ Standards Committee
- Trainer, auditor, consultant, instructional designer
- ASQ Fellow, ASQ CQA, former Certified Lead Auditor
- Recipient of several professional and business awards
- Former plant manager, business manager and venture manager for fortune 200 companies.

**IMPORTANT NOTE: My remarks are my personal remarks and not that of any organization that I belong.**



# OUR PLAN

- THINKING
- OBSERVATIONS
- AUDITING: PLAN, PERFORM, REPORT, FOLLOW-UP
  - ✓ OPEN-ENDED REQUIREMENTS
- AUDIT PROGRAM MANAGEMENT
  - ✓ AUDITOR COMPETENCIES: RISK-BASED THINKING, METRICS, MSA, PROCESSES, PROCESS APPROACH
- CONCLUSION



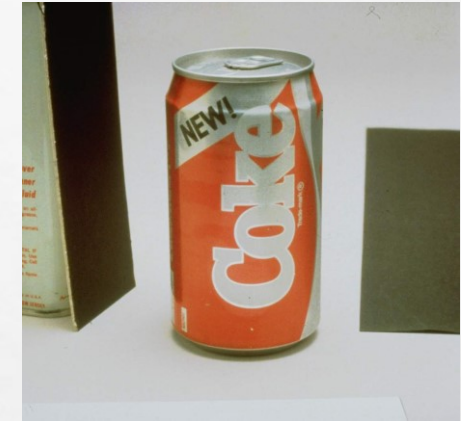
# ASQ TV VIDEO INTERVIEW

**JULY 18, 2014** I EMAILED ASQ THAT I HAVE FOUR MAIN AREAS OF INTEREST:

- 1. COMPETENCY** NEEDS FOR AUDITORS TO AUDIT THE NEW VERSION
- 2. FUNDAMENTALS OF MANAGEMENT CONTROL** SINCE NO PROCESSES REQUIRE DOCUMENTED PROCEDURES
- 3. CONFUSION** OVER DOCUMENTS, RECORDS AND DOCUMENTED INFORMATION
- 4. OVERALL PERSPECTIVE** OF THE QMS STANDARD

# TODAY: THINKING AND DISCLAIMERS

- NOT HERE TO BE A **CRITIC**
- THIS IS **MY VIEW** AND NOT THAT OF ANY ORGANIZATION THAT I AM A MEMBER
- MY PRIMARY **FOCUS IS ON AUDITING** THE MSS STANDARD
- DOCUMENTED INFORMATION WILL BE DOCUMENTS AND RECORDS
- DON'T SHOOT THE MESSENGER



1985





# WHY WOULD USERS LIKE THE NEW VERSION?

- **PERHAPS BECAUSE:**
  - **THERE ARE NO REQUIRED PROCEDURES WITH PRESCRIPTIVE STEPS**
  - **MANY OF THE REQUIREMENTS ARE SO OPEN-ENDED YOU COULD DRIVE A TRUCK THROUGH THEM**
    - **IE: LOOSELY INTERPRETED**
  - **THE FOCUS IS ON PERFORMANCE INSTEAD OF CONFORMITY TO REQUIREMENTS**

**Why is no one talking about how to audit the new management system standards?**

# OBSERVATIONS



- **PERFORMANCE FOCUS** {BEYOND QMS EFFECTIVENESS}
- AUDITING CLAUSES 4, 5, 6, 7, 9 AND 10 WILL BE THE **SAME OR SIMILAR** FOR ALL MSS
- SOME INDIVIDUALS ARE BLAMING CONFORMITY ASSESSMENT **PROBLEMS ON THE CHECKLIST**
- AUDITORS SHOULD **NOT FORCE MSS LINGO** ON AUDITEE ORGANIZATIONS. FOR EXAMPLE:  
DOCUMENTED INFORMATION AND CONTROL OF EXTERNAL PROVIDERS

# QUALITY AWARD - MBNQA

## ISO 9001:2015 QMS REQUIREMENTS

- 4.1 ORGANIZATION AND ITS CONTEXT
- 5 LEADERSHIP
- 5.1.2 CUSTOMER FOCUS
- 6 PLANNING
- 7 RESOURCES
- 8 OPERATIONS
- 9 PERFORMANCE EVALUATION
- 10 IMPROVEMENT

## CRITERIA FOR PERFORMANCE EXCELLENCE

- ORGANIZATION PROFILE
- LEADERSHIP
- CUSTOMER FOCUS
- STRATEGIC PLANNING
- WORKFORCE FOCUS
- OPERATION FOCUS
- MEASUREMENT, ANALYSIS AND KNOWLEDGE MGMT.
- RESULTS

*No Internal Auditing or CBs*



# FOR EXAMPLE:

2014 MBNQA: #4

THE **MEASUREMENT, ANALYSIS, AND KNOWLEDGE MANAGEMENT** CATEGORY ASKS HOW YOUR ORGANIZATION **SELECTS, GATHERS, ANALYZES, MANAGES, AND IMPROVES ITS DATA,** INFORMATION, AND **KNOWLEDGE ASSETS**; HOW IT LEARNS; AND HOW IT MANAGES INFORMATION TECHNOLOGY. THE CATEGORY ALSO ASKS HOW YOUR ORGANIZATION USES REVIEW FINDINGS TO **IMPROVE ITS PERFORMANCE.**

# CROSSOVER STANDARD



- **PERFORMANCE**

- ✓ **A.04 RISK-BASED THINKING, PAGE 21, ISO 9001:2015**

**“THE RISK-BASED THINKING APPLIED IN THIS INTERNATIONAL STANDARD HAS ENABLED SOME REDUCTION IN PRESCRIPTIVE REQUIREMENTS AND THEIR REPLACEMENT BY PERFORMANCE-BASED REQUIREMENTS.”**

- **FROM CLOSED-ENDED PRESCRIPTIVE REQUIREMENTS TO OPEN-ENDED RESULTS FOCUSED REQUIREMENTS**
- **RESULTS FOCUS LEADING TO IMPROVED PERFORMANCE AND AN EFFECTIVE MANAGEMENT SYSTEM {QMS, EMS}**

# PREPARING AUDIT ACTIVITIES - PLAN

- **PERFORM THE DOCUMENT REVIEW**
- PREPARE THE AUDIT PLAN
- ASSIGN WORK TO THE AUDIT TEAM
- PREPARING WORKING DOCUMENTS –CHECKLISTS-SAMPLING PLANS

ISO 19011

Plan what you do and do what you plan



# DOCUMENTED PROCESSES



QMS 4.4.1 : THE ORGANIZATION **SHALL DETERMINE THE PROCESSES NEEDED** FOR THE QUALITY MANAGEMENT SYSTEM AND THEIR APPLICATION THROUGHOUT THE ORGANIZATION, AND SHALL:

- A} DETERMINE THE INPUTS REQUIRED AND THE OUTPUTS EXPECTED FROM THESE PROCESSES;
- B} **DETERMINE THE SEQUENCE AND INTERACTION** OF THESE PROCESSES;
- C} DETERMINE AND APPLY THE CRITERIA AND METHODS (INCLUDING MONITORING, MEASUREMENTS AND RELATED PERFORMANCE INDICATORS) NEEDED TO ENSURE THE EFFECTIVE OPERATION AND CONTROL OF THESE PROCESSES;

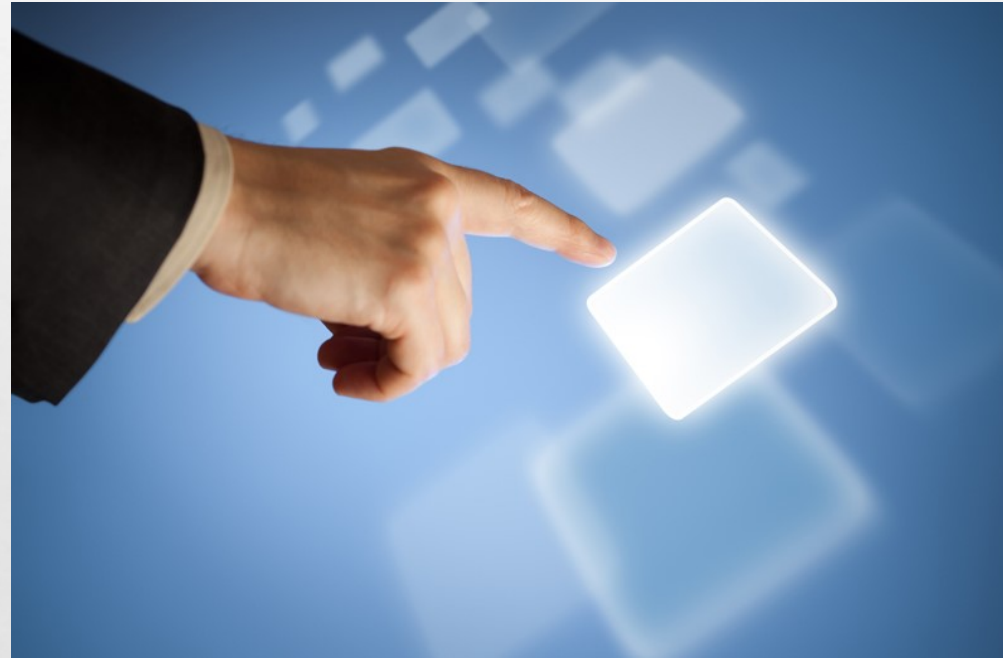
*Plan what you do and do what you plan*

# QMS PROCESSES?

- TRAINING PLAN
  - DOCUMENTED INFORMATION PLAN
  - COMMUNICATION PLAN
  - OPERATIONS
    - ✓ REQUIREMENTS FOR PRODUCTS AND SERVICES PLAN
    - ✓ DESIGN PLAN
    - ✓ PURCHASING PLAN
    - ✓ OPERATING PLAN
    - ✓ CONTROL OF PROCESS CHANGES PLAN
  - INTERNAL AUDIT PLAN
  - NONCONFORMITY CONTROL PLAN
  - CORRECTIVE ACTION PLAN
  - TOOLS
    - ✓ SCHEDULES, CHECK SHEETS, FLOW CHARTS, ETC.
    - ✓ TEMPLATES FOR MANAGEMENT REVIEW
- AGENDA

# DOCUMENTED INFORMATION

- QUALITY/ENVIRONMENTAL PLANS
- ACTIVITY PLANS
- CHECK SHEETS
- FLOW DIAGRAMS
- PROCEDURES



RT?  
Traceability?  
Editorial?  
Substantive?

- OTHERS?



# DOCUMENTED INFORMATION

## 7.5 DOCUMENTED INFORMATION

- 7.5.1 THE ORGANIZATION'S QUALITY/ENVIRONMENTAL MANAGEMENT SYSTEM SHALL INCLUDE:
  - A) DOCUMENTED INFORMATION **REQUIRED BY THIS INTERNATIONAL STANDARD**;
  - B) DOCUMENTED INFORMATION **DETERMINED BY THE ORGANIZATION AS BEING NECESSARY** FOR THE EFFECTIVENESS OF THE QUALITY/ENVIRONMENTAL MANAGEMENT SYSTEM.

Plan what you do and do what you plan

# CONDUCTING THE AUDIT ACTIVITIES

- PERFORMING DOCUMENT REVIEW **WHILE CONDUCTING THE AUDIT – WHY?**
  - ✓ AUDITOR IS BETTER ABLE TO ADJUST TO THE APPROACH FOR CONTROLLING DOCUMENTED INFORMATION
  - ✓ ACCESS AND SECURITY ISSUES ARE MINIMIZED
  - ✓ IDENTIFY PROMISED ACTIONS AND OUTPUTS SUCH AS A RECORD –RETAINED DOCUMENTED INFORMATION
- COLLECTING EVIDENCE AND VERIFYING REQUIREMENTS
- GENERATING AUDIT FINDINGS
- PREPARING AUDIT CONCLUSIONS

*Plan what you do and do what you plan*

# OPEN-ENDED REQUIREMENT



- TYPE I: **OPEN-ENDED PHRASES/WORDS**; SUCH AS: PERIODIC, TIMELY, PROMPTLY, WITHOUT UNDUE DELAY
- TYPE II: GENERALIZED STATEMENTS: **GENERALIZED OR ABSTRACT LEVEL REQUIREMENTS** TO CONTROL OR MANAGE A FUNCTION OF PROCESS; SUCH AS: ENSURE CONTROL OVER PROCESSES OR CARRY OUT PRODUCTION UNDER CONTROLLED CONDITIONS...
- TYPE III: **UNCLEAR OR UNDEFINED WORDS**. EXERCISE CARE
- TYPE IV: **NO TANGIBLE PRESCRIPTIVE REQUIREMENTS SPECIFIED**. ENSURE PURCHASED PRODUCT CONFORMS TO REQUIREMENTS

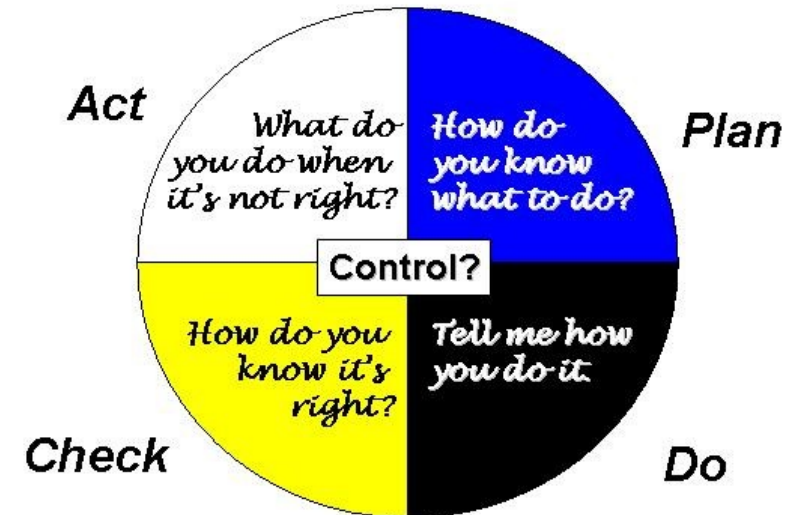
\* Russell, JP; Process Auditing and Techniques Guide, 1<sup>st</sup> edition 2003 and 2<sup>nd</sup> edition 2010)



# PROCESS AUDITING TECHNIQUES I

- PDCA TO VERIFY MANAGEMENT CONTROL

*Plan it - Do it - Check it – Act on it*



# AUDITING TECHNIQUES II

- OPEN-ENDED QUESTIONS FOR OPEN-ENDED REQUIREMENTS

- ✓ HOW DO YOU...

- TOOLS

- ✓ FLOW DIAGRAM

- ✓ SUPPLIER-INPUTS-PROCESS-OUTPUT-CUSTOMER MAP {SIPOC}

- ✓ TURTLE DIAGRAM

- ✓ FIGURE 1, PAGE VIII, ISO 9001:2015 OR FIGURE PAGE VII ISO 14001:2015

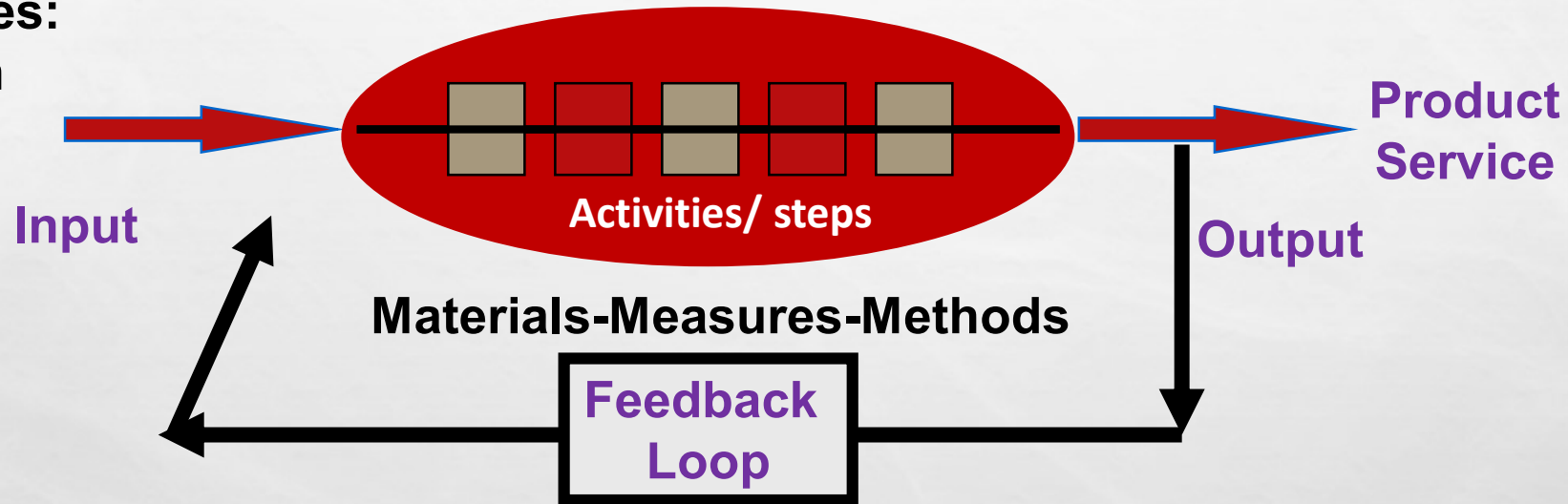
*QMS:  
Relevant ~21  
Appropriate ~20  
Consider ~20  
Necessary, extent, if ~28  
As applicable ~28*

# Process\*

ISO 9001:2015, Clause 4.4.1  
Verband der Automobilindustrie VDA 6.3

People-Equipment-Environment

Input Examples:  
Information  
Material  
Money  
Parts  
Etc.



ABC

PEEMMM

Note: Causes of Dispersion on the effect

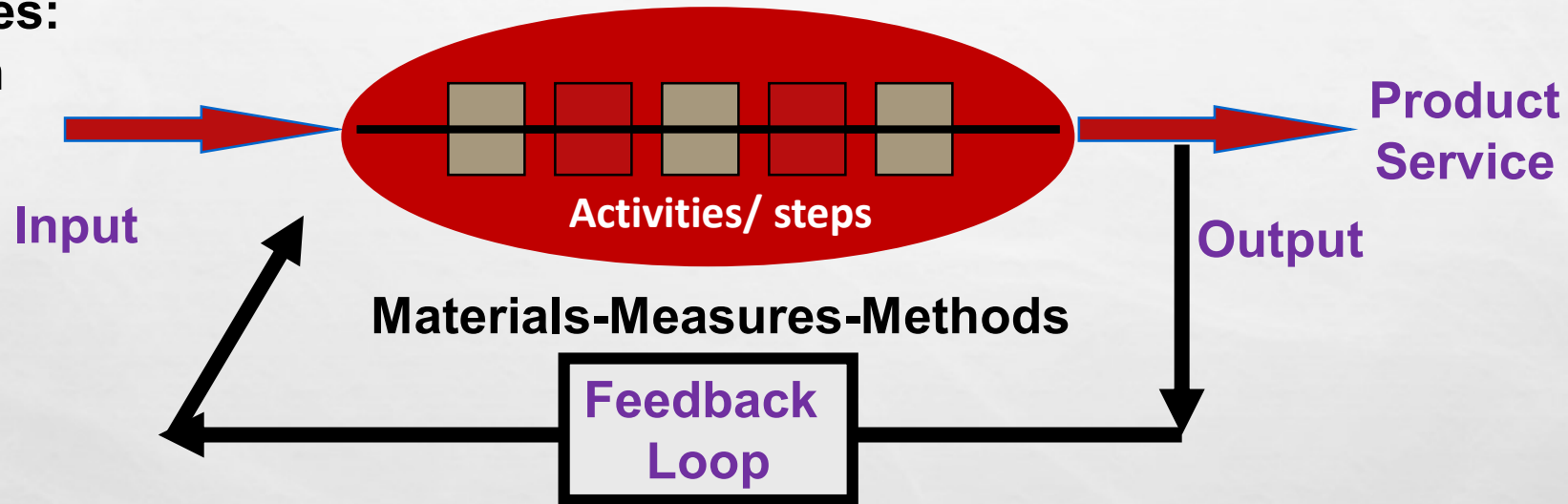
\* Russell, JP, Process Auditing Techniques Guide 1<sup>st</sup> Edition, 2003, ASQ Quality Press, page 7



# Process\*

People-Equipment-Environment

Input Examples:  
Information  
Material  
Money  
Parts  
Etc.



PEEMMM

\* Russell, JP, Process Auditing Techniques Guide 1<sup>st</sup> Edition, 2003, ASQ Quality Press, page 7

# REPORTING



The image shows a digital display titled 'Tides / Marées'. It lists the tide schedule for 'Today • Aujourd'hui'. The display shows three tide events: high tide at 8:59, low tide at 15:09, and high tide at 21:22. There is a colon ':' in the time column for the next row, suggesting a fourth tide event. The display also shows a sunset icon and time of 20:56 at the bottom right.

Tides / Marées	
Today • Aujourd'hui	
high • haute	8:59
low • basse	15:09
high • haute	21:22
	:
	20:56

- NONCONFORMANCE: ISO 19011 6.4.7 ALLOWS FOR GRADING NONCONFORMITIES
- CONFORMANCE: CONSIDER GRADING CONFORMANCE
  - ✓ PROCESS, **APPROACH. DEPLOYMENT, INTEGRATION**
  - ✓ RESULTS, **MEANINGFUL, CONTINUOUS, EXCELLENCE**
  - ✓ REACTIVE VS PROACTIVE, **6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES**
  - ✓ ON-GOING IMPROVEMENT, **10.3 CONTINUAL IMPROVEMENT AND 4.4.1 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES**
- COMMENTS/OBSERVATIONS REGARDING THE ORGANIZATION'S APPROACH AND MATURITY
  - ✓ INTENT
  - ✓ IMPROVING PERFORMANCE AND EFFECTIVENESS OF THE QMS
- OPPORTUNITIES FOR IMPROVEMENT

# AUDIT PROGRAM MANAGEMENT

- AUDITOR COMPETENCIES

- ✓ KNOWLEDGE OF MSS REQUIREMENTS
- ✓ PROCESS FUNDAMENTALS AND PROCESS APPROACH
- ✓ RISK-BASED THINKING **6.1 AND STANDARD IN GENERAL**

WHAT IF IT BOMBS AND WHAT IF IT TAKES OFF

TOOLS: FMEA, BRAINSTORM, PRIORITIZE, STRENGTH-WEAKNESS-OPPORTUNITY-THREAT {SWOT}

- ✓ METRIC FUNDAMENTALS – MEASURE PERFORMANCE/RESULTS. WHAT ARE GOOD/BAD METRICS?  
**RESULTS, OBJECTIVES, AND MONITORING, 9.1.1**
- ✓ MEASUREMENT SYSTEM ANALYSIS {MSA} – SOURCES OF ERROR WHEN TESTING **ISO 9001:2015**  
**CLAUSE 7.1.5**

*Examiners?*





# AUDIT RISK

- WHAT ARE THE RISKS?



# CONFORMITY VS PERFORMANCE

- **MODEL I: COMPLIANCE/CONFORMANCE ASSESSMENT**  
**{INSPECTION}**
  - ✓ COLLECT EVIDENCE TO VERIFY PRESCRIPTIVE REQUIREMENTS
  - ✓ PASS/FAIL, YES/NO
  - ✓ QUALITY MANUAL AND A PROCEDURE FOR EVERY CLAUSE
- **MODEL II: PERFORMANCE ASSESSMENT**
  - ✓ REVIEW PERFORMANCE AND THE EFFECTIVENESS OF THE MSS TO ASSESS PROGRESS/SUCCESS
  - ✓ SCORE PERFORMANCE
  - ✓ FOCUS ON RESULTS, NOT PROCEDURES



# **DIVORCE OR SEPARATION**

- **COMPLIANCE MARRIED CONFORMANCE**



# WHAT IS THE SCOPE OF ISO 9001?

- SPECIFIES QMS REQUIREMENTS WHEN AN ORGANIZATION
  - A} NEEDS TO DEMONSTRATE ITS ABILITY TO CONSISTENTLY PROVIDE PRODUCTS AND SERVICES THAT **MEET CUSTOMER AND APPLICABLE STATUTORY AND REGULATORY REQUIREMENTS, AND**
  - B} **AIMS TO ENHANCE CUSTOMER SATISFACTION** THROUGH THE EFFECTIVE APPLICATION OF THE SYSTEM, INCLUDING PROCESSES FOR IMPROVEMENT OF THE SYSTEM AND THE **ASSURANCE OF CONFORMITY TO CUSTOMER AND APPLICABLE STATUTORY AND REGULATORY REQUIREMENTS.**

**Requirements focus?**

# WHAT IS THE SCOPE OF ISO 14001?

- SPECIFIES EMS REQUIREMENTS THAT AN ORGANIZATION CAN USE TO ENHANCE ITS ENVIRONMENTAL **PERFORMANCE**.
- THE EMS STANDARD HELPS AN ORGANIZATION ACHIEVE INTENDED OUTCOMES. THE INTENDED OUTCOMES INCLUDE:
  - ENHANCEMENT OF ENVIRONMENTAL **PERFORMANCE**;
  - FULFILMENT OF **COMPLIANCE** OBLIGATIONS;
  - ACHIEVEMENT OF ENVIRONMENTAL **OBJECTIVES**.

# CONCLUSION

## Conformance/performance Assessment

- FOLLOW STANDARD AUDITING PRACTICES
  - ✓ CONSIDER DOING THE DOCUMENT REVIEW ONSITE IF AN ONSITE AUDIT
  - ✓ VERIFY RECORDS –RETAINED DOCUMENTED INFORMATION
  - ✓ **VERIFY** PROCESSES
- USE **PROCESS AUDITING** TECHNIQUES – PDCA, HOW DO YOU....,
- ORGANIZATIONS WILL NEED TO SHOW THEY ARE ACHIEVING **RESULTS** FROM AUDIT TO AUDIT – ESTABLISH BASELINE OR ASK FOR HISTORY
- UNDERSTAND AND BE ABLE TO **APPLY**
  - ✓ PROCESS APPROACH
  - ✓ RISK BASED THINKING AND TOOLS
  - ✓ SELECTION OF EFFECTIVE METRICS TO MONITOR



# AUDITOR COMPETENCIES

- **WHAT IS THE WISE THING TO DO?**
  - ✓ **BASED ON YOUR PAST EXPERIENCE**
  - ✓ **BASED ON YOUR CURRENT EXPERIENCE**
  - ✓ **BASED ON YOUR FUTURE GOALS AND EXPECTATIONS**





# RESULTS COME FROM CHECKING, NOT EXPECTING.

**Russell, JP, Continual Improvement Assessment: Promoting and Sustaining Business Results, Page 2, 2004, ASQ Quality Press, Milwaukee, WI.**



# Thank you for joining me



Web-based training at: [www.QualityWBT.com](http://www.QualityWBT.com)

**Management Briefing** for Transitioning to ISO 9001:2015

ISO 9001:2015 **Transition Training**

ISO 9001:2015 Requirements from A to Z

**Metric Fundamentals:** The Right Measurements Improve Performance

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