Now that We Are ISO Certified, What’s Next?

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Jeffrey Hewes received his B.S. in Industrial Organizational Psychology at Southeast Missouri State University and is currently the Quality Manager at NOVA Marketing Services a subsidiary of The MATLET Group. Since joining NOVA Marketing, he was instrumental in leading NOVA’s successful certification of ISO 9001:2008 and is in spearheading the implementation of ISO 27001:2005. Jeff brings over 20 years of experience in the managing ISO based Quality Systems. Jeff is also a certified Lean Six Sigma Black belt and a third generation Quality Manager. His father, Walter Hewes was a graduate of Bryant University.

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Randy Pittman works for National Quality Assurance USA (NQA-USA), an independent 3rd party certification registrar. For the past 8 years Randy has primarily served within the business development group, developing and delivering a unique customer service based consultant referral program for NQA clients. With a B.S degree in Geo Physical Science Randy began his career as an organic chemist for an environmental testing firm. Randy later returned back to the family business as a project manager which included logistics design and coordination for construction projects; both domestic and international. He has experience with risk management relating to ISO 31000 and business continuity methodologies. He volunteers his professional and quality management skills as the North East “Senior Director” for a national non-profit organization.

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ISO 9001

If you follow the standard’s requirements but not the intent, the standard won’t provide much value. It's the intent that counts.

1. Enhance customer satisfaction in supplier-customer relationships
2. Continual Improvement
3. ISO can be a stepping stone to other standards
ISO 9001
Management System is the base for many other standards
ISO comes in many different shapes and sizes

- ISO 9001: Quality Management
- ISO 14000 Environmental Management
- ISO 27001 Information Security System Standard
- OHSAS 18001 Occupational Health and Safety Standard
- TS 16949 Automotive Quality Standard
- AS 9001 Aircraft Quality Standard
- ISO 50001 Energy Management
- ISO 22000 Food Safety Management
## 1 - INTEGRATED MANAGEMENT POLICY

1.1 - Management commitment
   - Continuous improvement

## 2 - PLANNING

2.1 - Identification of product requirements, aspects, impacts, hazards and risks and their assessment
   - 5.1
   - 5.2
   - 7.1
   - 7.2

2.2 - Identification, access to and updating of legal requirements and other requirements of Stakeholders
   - 4.3
   - 4.4
   - 4.5

2.3 - Definition of objectives, targets and Programmes of IMS management and improvement
   - 5.4
   - 5.5
   - 8.5

2.4 - Definition of the plans of response to emergency situations
   - 8.3

## 3 - IMPLEMENTATION AND OPERATION

3.1 - Resources, organizational structure, roles, responsibilities and authority
   - 5.1
   - 5.5
   - 6.1
   - 6.3

3.2 - Training, awareness, competences and qualifications
   - 6.2
   - 6.2
   - 4.4
   - 4.4

3.3 - Communication, participation and consultation of the Stakeholders
   - 5.3
   - 7.3
   - 4.3
   - 4.3

3.4 - QMS Management System documentation
   - 4.2
   - 4.4
   - 4.4

3.5 - Control of documents
   - 4.2
   - 4.4
   - 4.5

3.6 - Product realization
   - 7.1
   - 4.6
   - 4.6
   - 4.5

3.7 - Operational control
   - 7.5

## 4 - CHECKING AND CORRECTION

4.1 - Performance monitoring and measurement of processes and products
   - 8.1
   - 8.2
   - 8.4
   - 4.5

4.2 - Evaluation of compliance
   - 8.2
   - 8.4
   - 4.5
   - 4.2

4.3 - Incident investigation
   - 4.5

## 5 - MANAGEMENT REVIEW

5.1 - Critical analysis and combined auditing
   - 8.3
   - 8.5
   - 4.6

## CONTINUOUS IMPROVEMENT OF THE IMS QES
Continual Improvement

• Clause 8.5.1, states:
  The organization shall continually improve the effectiveness of the quality management system (QMS) through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.
Continual Improvement

ISO 9001 provides the tools for Continual Improvement:

– Quality Policy and Quality Objectives
– Analysis of Data
– Management Review
– Audit Results
– Corrective actions
– Preventive Actions.
Quality Policy and Quality Objectives

If your quality policy and related quality objectives (clause 5.4.1) are not being achieved, then opportunities for Continual Improvement exist. These opportunities should surface at management review when quality measurement results are reviewed to quality objectives.
Companies Quality Policy

- Ask Managers what is important for XYZ Company
- Have the Managers write them on post it notes and place them all over the wall
- Have the managers categorize them in logical sequence
- Create short sentences for the top 5 categories
- Ensure these objectives are measurable
- The sixth should always include **profitability**
- Finally have the highest authority author the Quality Policy
Quality Policy and Quality Objectives

QUALITY POLICY

NOVA Marketing Services is committed to meeting and exceeding our customer’s expectations for service, on time delivery and quality. We strive to continuously improve the performance, quality and value of our products and services through innovation and technological excellence.

To achieve these goals, NOVA has established the following Quality Objectives:

- Safety
- Customer Satisfaction
- On Time Delivery
- Developing Human Resources
- Continual Improvement of the Quality System
- Profitability

Our commitment is achieved through the active participation of all our Associates in the NOVA Quality System.

Kathy Abbott
Kathy Abbott
Analysis of Data

Analysis of QMS data (clause 8.4) may provide significant information on operational performance and improvement opportunities. Management must review and make decisions and take actions on the results provided by such data.
You Can't Manage What You Don't Measure

- Key Performance Indicators (KPI) should tied to your Quality Objectives.
- KPI can be highly effective for exposing, quantifying and visualizing waste
- KPI are highly effective motivators.
- SMART goals, which are Specific, Measurable, Achievable, Realistic, and Time-Specific
- KPI should be available to all levels to maintain focus.
Visual Management Systems
Management Review

The purpose of conducting management reviews (clause 5.6) of the QMS is to gauge the health of the QMS. The review must determine QMS suitability, adequacy and effectiveness. (DASHBOARD)

Top management must evaluate QMS and take appropriate actions.
Required Inputs

– Results of audits
– Customer feedback
– Process performance and product conformity
– Status of Preventive and Corrective Actions
– Follow-up actions from previous management review
– Changes that could affect the Quality Management System
– Recommendations for improvement
Required Outputs

- Improvement of the effectiveness of the QMS and its processes
- Improvement of product related to customer requirements and
- Resource needs
Keys to Management Review

- At first, they will run long
- Start Monthly to maintain focus
- Align Key Performance Metrics to Quality Objectives
- Celebrate success and focus on improvement
- Every Manager should have a voice
QMS AUDIT

Results of product, process and QMS audits (clause 8.2.2) usually provide many opportunities to improve QMS effectiveness and efficiency. The management representative must report these opportunities to top management for management review.
Internal Audit Flow

Audit Scheduling  Audit Planning  Audit Management  Audit Reporting  Audit Verification
Internal Audits

- Select auditors wisely
- Auditors can not audit their own work
- Use audit checklists to ensure consistency
- Combine requirements to reduce the number of audits
- When collecting evidence documents or records trump verbal.
- Inform process owner of findings as they happen
- Include the top authority in the report out
- Report Internal Audits in management review
- Combine Internal Audit findings with Corrective and Preventive Action System
Corrective Actions

**Corrective action** (clause 8.5.2) is action taken to eliminate the cause of detected nonconformity to prevent recurrence.

**NOTE:** Any customer complaint is a nonconformity and should require a Corrective Actions

Most business experience problems on a day to day basis (nonconformities in quality management lingo) that may relate to - products; QMS processes; resources; suppliers and outsourced work; product shipped to customers; customer complaints; etc.
Preventive Action

Preventive action (clause 8.5.3) is action taken to eliminate the cause of a potential nonconformity or other undesirable situation, to prevent occurrence.

Examples:
- Risk Analysis
- Employee Suggestions
Corrective and Preventive Actions

1. Identification
2. Evaluation/Interim Action
3. Investigation
4. Root Cause Analysis
5. Action Plan
6. Implementation
7. Follow up
Why Do Root Cause Analysis?

“Just fix it, there is too much to do.”
“We don’t have time to think, we need results now.”

• Reality - fix symptoms without regard to actual causes

• Root Cause Analysis - structured and thorough review of problem designed to identify and verify what is causing the symptoms
CAPA TEAM

- Develop a cross functional group of expert problem solvers and make them a team that reviews, approves and verifies the effects of CAPA.

- Things to train the team on Root Cause Analysis
  - Work on the cause – NOT the symptoms or low-hanging fruit
  - Fishbone diagram is useful for identifying root causes
  - Use the 5 why’s
  - Cause and Effect Diagram
Levels of CAPA

- **Level 1:** No action-Interim Action solved the issue

- **Level 2:** Awareness- Quality Awareness of the issue is sufficient for resolution.

- **Level 3:** Action: Requires Root Cause Analysis and Permanent Action to prevent recurrence.

- **Level 4:** Advanced- Requires multi departmental resources or additional capital to resolve the issue.