

BUSINESS ASSURANCE

WEBINAR: ISO 9001:2015 TRANSITION EXPERIENCES

21 February 2017

DNV GL and Consultant are acting in cooperation to provide this Webinar purely as an informational session to attendees and no relationship should be implied between DNV GL and Consultant. Participation in this Webinar does not construe a request for auditing or certification services nor implies any relationship between DNV GL and Consultant. DNV GL remains impartial and does not recommend or endorse individual consulting companies or seek to influence clients in deciding whether to use a consulting company or which to select.

OUR PURPOSE

TO SAFEGUARD
LIFE, PROPERTY
AND THE ENVIRONMENT

DNV GL - Global reach – local competence



150+

years

300+

offices

100

countries

14,000

employees

DNV GL :: Focused on your future

Tomorrow's successful companies will create value by meeting the world's **social, economic** and **environmental** needs.

We help you build **Sustainable Business Performance** through our global certification, verification, assessment and training services.

SUSTAINABLE VALUE and STAKEHOLDER TRUST

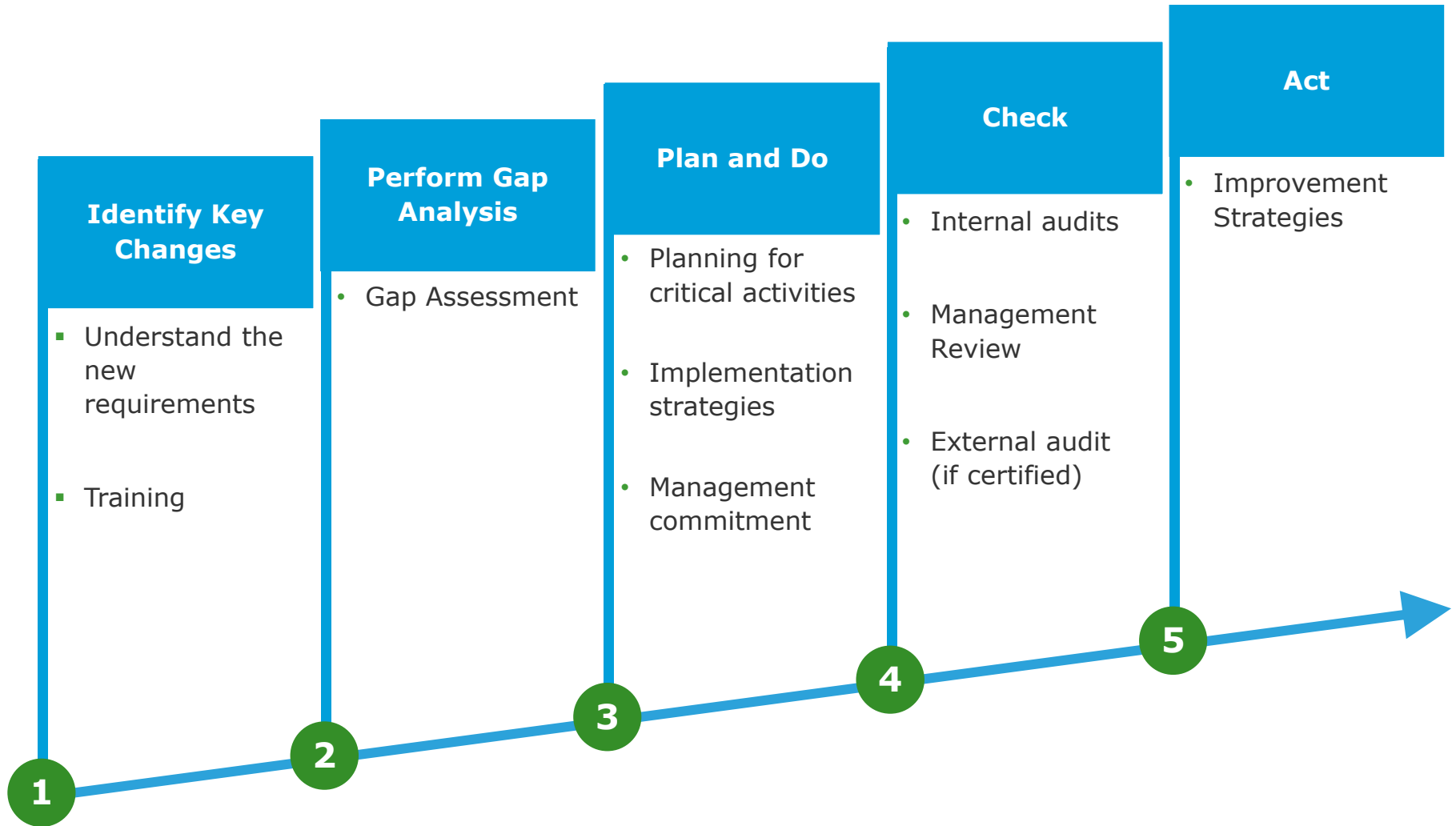
A Shared Ambition



- DNV GL:
 - Sustainability in everything we do. Partnering with our customers to build sustainable business performance and stakeholder trust, contributing to a safe and sustainable future.
- ISO:
 - Their vision is for the ISO standards to contribute to innovation and sustainable development

“In the longer term, we can expect sustainability to become a fundamental principle for ISO standards in just the same way as market relevance.”

Step by Step Transition



Transition Requirements

***DNVGL Target Deadline for Transition Audit:
15 June 2018***

Transition to ISO 9001:2015 / ISO 14001:2015

▪ Important Dates

- 15 March 2017
- All new certifications or re-certifications will be issued against ISO 9001:2015

- 15 September 2018
 - ISO 9001:2008 mandatory expiration date, which is the withdrawal date of both standards
 - Certificate is issued after an upgrade surveillance or recertification audit against ISO 9001:2015 has been performed

Additional Resources

- DNV GL Resources:
 - Live and OnDemand Webinars
<https://www.dnvgl.us/assurance/webinars/index.html>

 - Interpretive guidelines to ISO 9001:2015
 - <http://www.dnvglstore.com/product-p/1796-int9001.htm>

 - Training (Public and Private)
<https://www.dnvgl.us/assurance/Training/qualitytraining.html>

 - Certification Resource Center
<https://www.dnvgl.us/assurance/Management-Systems/CRC/index.html>

BUSINESS ASSURANCE

3 Hotpoints That Make ISO 9001:2015 The Best ISO 9001 Standard Yet

A presentation about ISO, getting audited, and some updates that make ISO 9001:2015 version better

21 February 2017

In 2000, our desire was to create a new consulting methodology that broke the mold. We wanted to create something that contradicted the consulting wisdom of the time. We wanted our clients to get certified in the shortest possible time, yet in a sustainable way. The methodology needed to be robust, but easy to implement. By 2004 we had our methodology. Ultimately, here's what we discovered. The more we obsessed on what we now call "Personalization", the better our outcomes. Since then, hundreds of satisfied clients have been certified in a very short space of time, without the need for any further consulting help. Desire achieved!

Before We Begin...

- Any good story requires a back story...

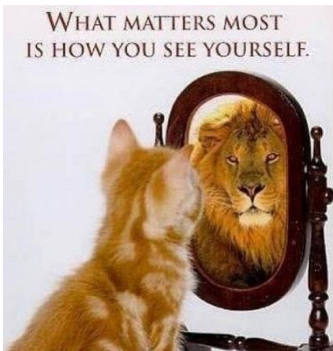
What do you want?



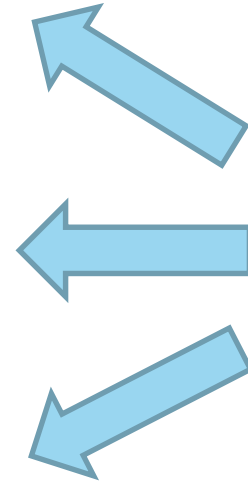
Company runs well



That contract



Feel good about yourself



Can ISO 9001:2015 help??

About ISO

- ISO is a word. It means “equal”
- ISO creates over 21,000 standards
- They are not government-funded
- They make money from selling the best standards
- ISO 9001 is their best-selling standard

What does ISO 9001 have going for it?

- Close to worldwide recognition
- Governments and large organization specify it
- Organizations want it

How does ISO make the best management system standards?

- Fusion the best minds and real people

Best Minds

- Where do these phrases come from?
 - Quality?
 - Management system?
 - Plan do check act?
 - Continual improvement?
 - Leadership theory?

Teams and Systems Thinking

“94% of problems in business are systems driven and only 6% are people driven.”

~ W. Edwards Deming

1900 – 1993



Deb Nystrom, REVELN.com

Real People Like You and Me

- ISO Technical committee 176
- Made up of many volunteers
- Representation of different backgrounds and different types of organizations

Good Management Practice

- Most good forward moving companies are already 70 to 90% ready for ISO certification

Generic

- In order to have the biggest audience, ISO 9001 needs to be generic

Your language	ISO 9001 generic language
Sales	Requirements for products and services
Prototyping	Design validation
Suppliers and purchasing	Control of external provided processes, products and services
Traveler or job card	Identification
Returns	Postdelivery activities
Mission statement	Quality policy
Business plan	Strategic direction
“OH NO, let’s do something about that”	Risk and planning

Sounds good, but what do you get?

Generic nature of
ISO 9001



Previous bad experiences
of others / faulty thinking



SPELLBOUND!



Faulty thoughts of a consultant



Faulty thoughts of an auditor

A Story About Being SPELLBOUND

- 150 person organization
- \$300,000 on consultants and auditors
- Progress: going backwards

Another Story About Being SPELLBOUND

- 30 person organization
- Preferred contractor of the ADF (Australian Defence Force)
- Progress: Feel like giving up

What should it look like?

I'm going to apply
ISO 9001 to be a
better business



I don't need
your negativity

**SMARTER
YOU**



A consultant that is
helpful and knows ISO 9001

A streetwise auditor that
knows ISO 9001

Strategic Direction: Fineprint

- Only gets a passing mention in ISO 9001:2015
 - 0.3.1 Process approach helps achieve your strategic direction
 - 4.1 Understanding organization and its content: The context of your organization (internal and external issues) should be relevant to your strategic direction
 - 5.1.1 General (Leadership and commitment): leaders to ensure policy and objectives are compatible with the strategic direction of the organization
 - 5.2.1 Quality policy: Quality policy to be appropriate strategic direction of the organization
 - 9.3 General (Management Review): a review at planned intervals to ensure that quality management system aligns with the strategic direction of the organization

What does strategic direction look like?

Guiding principles

Mission

Objectives

You're already doing it!

About us

Planning

Strategizing

Risk

What is risk in ISO 9001:2015?

- A risk assessment such as in OHSAS 18001:2007 or ISO 31000:2009?
- What happens before a preventive action (or an action to eliminate potential issues)?
- Could be these things, but mostly it is mentioned in the auditable sections of ISO 9001:2015 in relation to the context of the organization...

Risk in ISO 9001:2015 : Fineprint

1. 4.4 Quality management system and its processes: The organization will address the risks and opportunities identified in 6.1 as part of the quality management system
2. 5.1 Leadership and commitment: A leader uses and promotes risk-based thinking
3. 6.1 Actions to address risks and opportunities: 6.1.1 determine risks and opportunities when considering issues and requirements (from 4.1 and 4.2)
4. 6.1 Actions to address risks and opportunities: 6.1.2 determine actions to address the identified risks and opportunities from 6.1.1
5. 9.1.3 Analysis and evaluation: Determine the effectiveness of these actions from the above step (4) as part of analysis and evaluation
6. 9.3.2 Management review inputs: You need to perform the above step (5) as part of your management review
7. 10.2 Nonconformity and corrective action: If necessary, update risks and opportunities as part of corrective actions.

ISO 9001:2015 Appendix (A.4) - Phew

- "...Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards."
- "...Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks."

Risk and Strategic Direction in Real Life: Example 1

- The situation
 - 150 person organization
 - Already R2 certified
 - Needs ISO 9001
- Background: I have been trying to explain risk and strategic direction to the ISO person, but both of us know that we have to explain it to the CEO...

Let's Take a Break, Regarding the ISO Person...

- In ISO 9001:2008 top management shall appoint a member of management to be the Management Representative
- In ISO 9001:2015, the role of Management Representative is no longer named but in clause 5.3, but the role is still there. Why?
- Refer to ISO 9001:2015 clause 5.1.1 "Top management shall demonstrate leadership and commitment with respect to the quality management system by
 - a) taking account for the effectiveness of the quality management system
 - And so on...

Back to Risk and Strategic Direction

- CEO walks in unannounced on day 2:
 - CEO: “When are we getting certified?”
 - Me: “You’ll get certified by ... (Giving some long explanation about dates and all of the requirements that need to happen in the meantime).”
 - Me: “let me explain about risk and strategic direction...”
 - CEO: “We just spent \$150,000 doing that...”
 - ISO Appointee: “When?”
 - Me: “Great, let’s move on ”

Risk and Strategic Direction in Real Life: Example 2

- The situation
 - 200 person organization
 - Major client requires ISO 9001 certification
- Background: a few months earlier I expend almost an hour talking about risk, strategic direction, business plans, strategic plans and anything else related to try explain the requirement. The ISO person was **SPELLBOUND**

Risk and Strategic Direction in Real Life: Example 2

- ISO auditor through the ISO person: “Where is our risk assessment? The auditor says I need to do a risk assessment for quality just like with health and safety (OHSAS 18001: 2007)”
- Me: “Risk assessment is not a thing in ISO 9001” ... “did you address strategic direction in the management review?”
- ISO person: “We had the meeting but we didn’t get to that part”

Let's Take a Break...Regarding the Management Review

- In ISO 9001:2015, clause 9.3, “Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization”
- I tend to call the management review a meeting, but it’s not necessarily a meeting as it is a review of data to determine the effectiveness of the quality management system
- I haven’t counted, but many clauses are met through clause 9.3
- Lesson: don’t just have a management meeting, address every single clause in 9.3.2

Back to Risk and Strategic Direction in Real Life: Example 2

- Me continuing: “Remember how we spent a while in the beginning talking about risk, business plans, etc.?”
- ISO person: “Wait, about halfway through last quarter we did a business plan”
- Me: “Great, that’s it, show the auditor that”

- Prologue: Auditor accepts business plan and client gets certified

Risk: What does ISO 9001:2015 say about a business plan?

- Context and risk. Basically a SWOT analysis- (Strengths, Weaknesses, Opportunities, and Threats):
 - Determine your context (4.1) including external and internal issues such as market share, legal, competition, and the needs and expectations of interested parties (4.2) e.g. customers, employees, shareholders, etc.
 - Determine risks and opportunities in order to address your context (6.1.1)
- Determine actions to address the identified risks and opportunities (6.1.2)
- Monitor, evaluate and report the effectiveness of the actions taken to address risks and opportunities (9.1.3 Analysis and evaluation)
- Review changes in external and internal issues (9.3.2 Management review inputs)

Risk and Strategic Direction: Final Thoughts

- It probably doesn't need to be said, but this process needs to be legitimate and genuine. Don't just do it for the auditor
- It could look like:
 - A \$150,000 business plan
 - A meeting at the end of the year to plan out the next year
 - However you want it to look, just apply the clauses
- You could use brainstorming or whiteboarding. If whiteboarding, take a photo of the whiteboard before you clear it
- For each action, I suggest you identify a responsible person and the deadline for completion of the action
- Remember appendix 4? Risks and actions do not need to be documented.

POLICY, OBJECTIVES, and PLANS

- Think of the following clauses from ISO 9001:2015 as one process:
 - 5.2 Policy; and
 - 6.2 Quality objectives and planning to achieve them
- In ISO 9001:2015, the information on objectives and plans is more detailed than any previous version of ISO 9001. It is more in line with the intent of OHSAS 18001:2007, ISO 14001:2004 and ISO 14001:2015

POLICY, OBJECTIVES, and PLANS

- Quality Policy (5.2):
 - An umbrella statement that encapsulates the best of the whole business in one statement. Some of the best quality policies have already been documented in the “About Us” part of an organization’s website
 - Personal example: “I will strive to be fit and healthy”
- Objectives (6.2.1):
 - Measurable statements, consistent with the quality policy
 - Personal example continued: “place in the top 100 of the city marathon by 2018”
- Planning to meet objectives (6.2.2):
 - What, who, when and how objectives will be met
 - Personal example continued:
 - “Join a marathon club in January 2017”
 - “Engage a marathon coach by February 2017”
 - Etc.

6.2 of ISO 9001:2015 : Quality Objectives and Planning to Achieve Them

- Objectives shall:
 - Be consistent with the quality policy
 - Be measurable
 - Take into account applicable requirements
 - Be relevant to conformity of products and services and to enhancement of customer satisfaction
 - Be monitored
 - Be communicated
 - Be updated as appropriate
- The organization shall maintain documented information on the quality objectives

Suggestion for Objectives, Start with 9.1 of ISO 9001:2015

- 9.1 General (Monitoring, measurement, analysis and evaluation)
- The organization shall determine:
 - a) what needs to be monitored and measured;
 - b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
 - c) when the monitoring and measuring shall be performed;
 - d) when the results from monitoring and measurement shall be analyzed and evaluated.

Examples of Things that Could be Monitored or Measured

- Total hours of work
- Complaints
- On time delivery
- Budgets
- Performance of subcontractors
- Performance of vendors
- Client satisfaction
- The number of corrective actions
- Conformance to the quality management system
- Employee performance
- Risks and opportunities
- Completion of objectives
- Completion of action items from the strategic plan
- Servicing performance
- Returns
- Shipping dates
- Product conformity
- Employee satisfaction
- Performance and effectiveness of the quality movement system
- The effectiveness of training
- Etc.

How you Could Combine 9.1.1 (Monitoring and Measurement) with 6.2.1 (Objectives)

What needs to be monitored and measured	Objective if applicable	Monitoring and measurement method	Frequency of monitoring and measurement	When reported, analyzed and evaluated
Shipment of product to customer	On-time shipment	Monitor data on the Action Log	Ongoing	Monthly meeting
Product conformity	No quality complaints in the month	Monitor data on the Action Log	Ongoing	Monthly meeting
Conformance to the QMS	Zero major corrective actions from the certification body	Internal audit and certification audit reports	Annual	Management review
Customer satisfaction	Zero negative customer ratings	End of job customer surveys	Every returned survey	Monthly meeting

6.2 of ISO 9001:2015 : Quality Objectives and Planning to Achieve Them – cont.

- When planning how to achieve its objectives, the organization shall determine:
 - What will be done
 - What resources will be required
 - Who will be responsible
 - When it will be completed
 - How the results will be evaluated

Suggestions for Planning to Meet Objectives

- Suggest planning to meet objectives as part of the management review
- You can set plans to meet your objectives in Outlook i.e. calendar or tasks
- You can have your plans as part of other action items from your management review or on a separate sheet
- Always monitor implementation and deadlines of plans to ensure that they are met or a new date set.

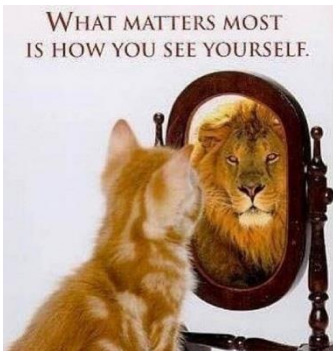
So, what do you want?



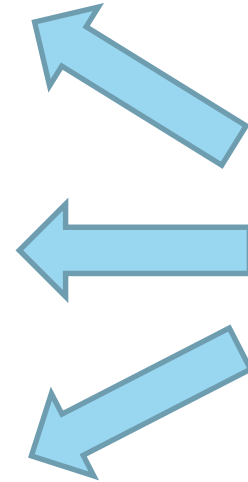
Company runs well



That contract



Feel good about yourself



ISO 9001:2015
can help!!

Contact Us

Manuel Marco, Director, Western Territory Sales
Manuel.Marco@dnvgl.com
(949) 521-0298

Damon Anderson, Principle, Compliancehelp Consulting, LLC.
Damon@quality-assurance.com
(877)238-5855

Click on the links below for more information:



Certification Resource Center

Bridging the knowledge gap for transitions to the new standards



Quality Management

Demonstrates your commitment to quality and customer satisfaction.



Easy Button Transfer

Transfer your certification without the hassle

Why you should use us...

Compliance help
iso consulting

- ISO 9001 Quality
- ISO 14001 Environmental
- OHSAS 18001 Safety
- ISO 13485 Medical Devices
- ISO 17025 Testing & calibration
- AS9100 Aerospace
- TL9000 Telecommunications
- ISO 20000 Information Technology
- R2 Electronics Recycling
- FDA Requirements
- CE Mark

What we do.

Q	E	M	S
ISO 9001 Quality Mgmt.	ISO 14001 Environmental Mgmt. Systems	ISO 13485 Medical Devices	OHSAS 18001 OHS Mgmt. Systems

Plus other Standards and Certifications.