Transitioning from ISO 9001:2008 to ISO 9001:2015

Kaizen Consulting

www.kaizengoal.co.nz

Presented by: Sean Banayan

Presented on: 18th October 2017

Craig Thornton

Chief Marketing Officer, Mango Limited

craig@mangolive.com

New Zealand

+64 29 377 5444

@mangolimited

LinkedIn

Blog – www.mangolive.com

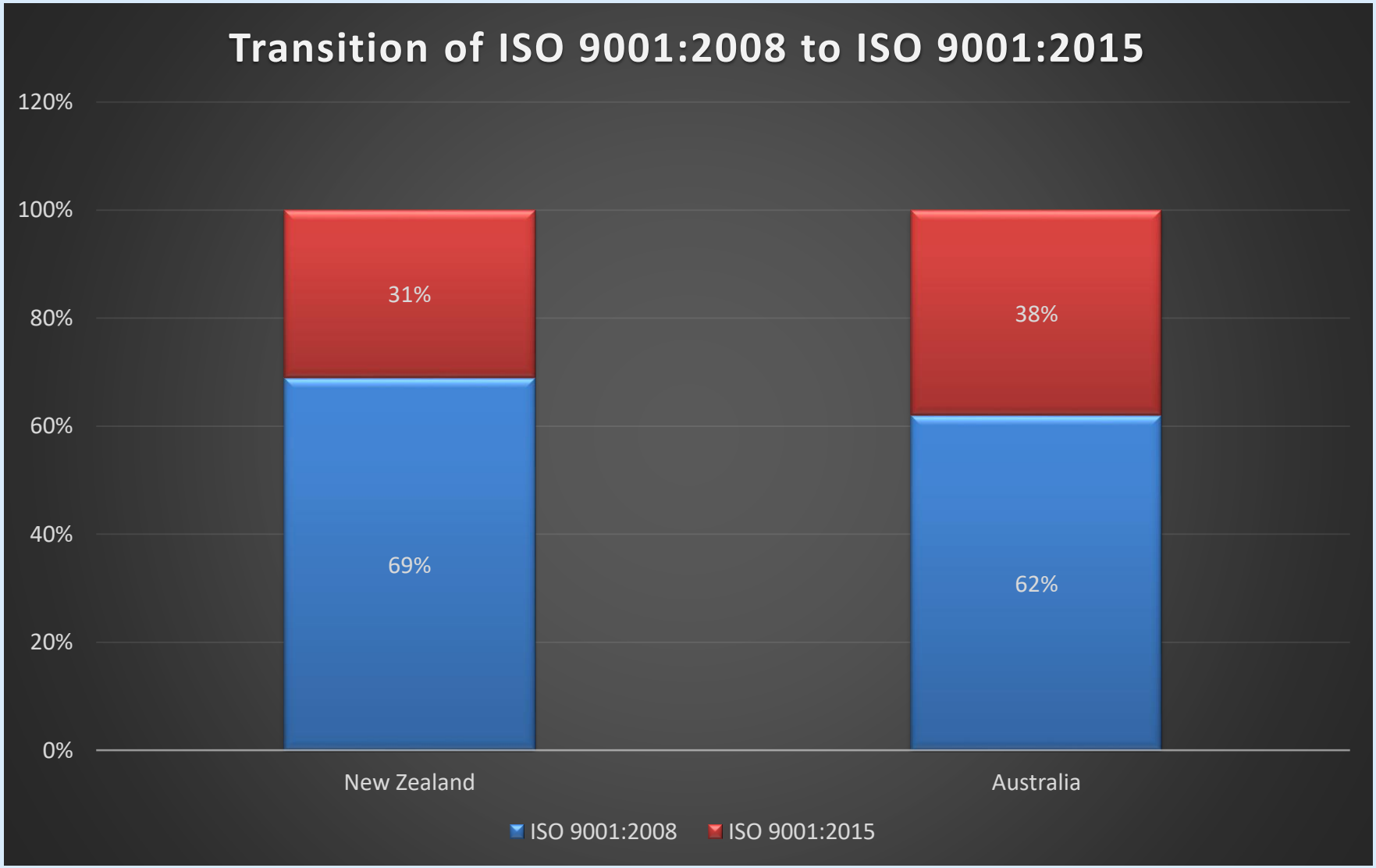
Kaizen Consulting

www.kaizengoal.co.nz

- ***Interact with the presenter anytime – ask questions***
- ***Use the question box on your go-to-webinar application.***
- ***Slides will advance automatically throughout the webinar***
- ***Recording of this webinar will be sent out in 24 hrs***
- ***The slide will be sent to you too***
- ***Please share the presentation with your colleagues***

Kaizen Consulting

www.kaizengoal.co.nz



Sean Banayan

Business Consultant, Kaizen Consulting

- Sean@kaizengoal.co.nz
- +64 27 511 9212
- LinkedIn
- Website – www.kaizengoal.co.nz

Recent Implementations

Kaizen Consulting
www.kaizengoal.co.nz

Recent three companies assisted to transition to ISO 9001:2015 standard:

ETEL LIMITED , Auckland
ETEL IS A LEADING NEW ZEALAND MANUFACTURER OF DISTRIBUTION TRANSFORMERS

Gallagher Group Limited, Hamilton
Global leader in the innovation and marketing of animal management and security solutions.

Gallagher Fuel System, Marton
Market leader of fuel dispense systems for service stations throughout Australasia.

Agenda

Kaizen Consulting
www.kaizengoal.co.nz

1) *ISO 9001 Overview*
   a) *Purpose*
   b) *Why has the standard been revised?*
   c) *Transition Timeline*
   d) *What remains the same?*
2) *Key Changes*
3) *Transition from ISO 9001:2008 to 2015 version*
4) *Transition is an opportunity*
5) *Questions*

ISO 9001 Main Benefits

Kaizen Consulting
www.kaizengoal.co.nz

1. ISO 9001 provides a set of uniform requirements for quality management system. It reflects a good level of professionalism for an organisation.

2. Confirms that the organisation is complying with any regulations applicable to those products or services.

3. Enhance customer satisfaction, and achieve continual improvement of its performance.

4. It certifies that the organisation ensures that its products or services satisfy the customer quality requirements and expectations

Overview – Why has the standard been revised?

Kaizen Consulting
www.kaizengoal.co.nz

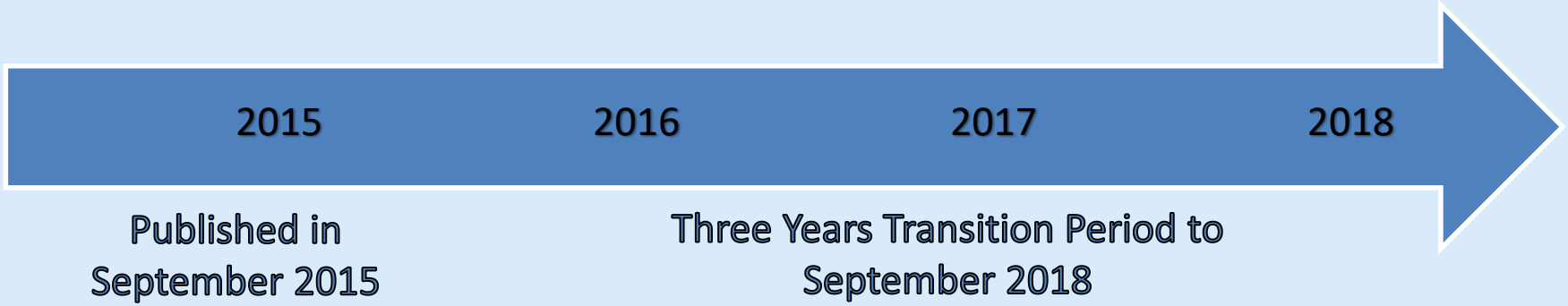
1. *ISO standards are reviewed and revised (if needed) every 7 years. ISO needs to reflect industry changes in order to stay relevant.*

2. *ISO 9001:2015 standard follows the same overall structure as other ISO management system standards (Annex SL).*

3. *Challenges faced by business & organisations has changed due to globalisation and operation of complex supply chain.*

Overview – Transition Timeline

Kaizen Consulting
www.kaizengoal.co.nz



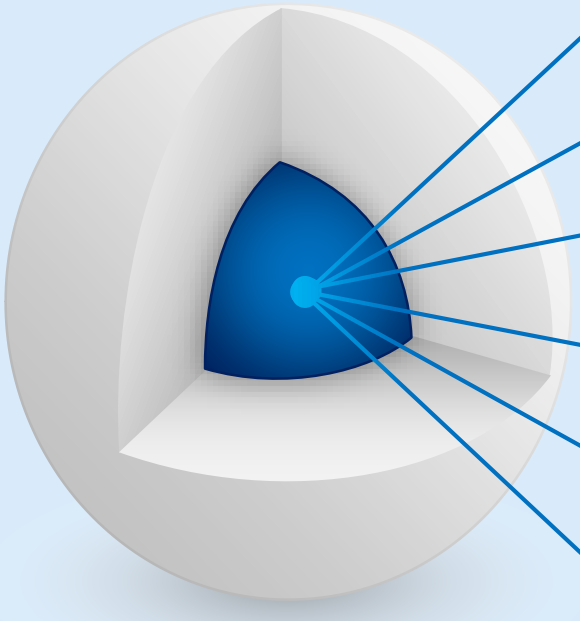
It is important to understand that your organisation's ISO 9001:2008 certification will no longer be valid as of September 14, 2018.

As ISO 14001 also has the Annex SL as its core text and high level structure, any learning you undertake in preparing for the revision to ISO 9001:2015 is also likely to help you through the revision to ISO 14001.

In the future when ISO 45001 (the new ISO standard for occupational health & safety, set to replace OHSAS 18001) is issued, it will also use the same core text and high level structure in Annex SL.

Overview – What remains the same?

Kaizen Consulting
www.kaizengoal.co.nz



- Management Review
- Corrective Actions
- Customer Satisfaction
- Control of Nonconforming Product
- Internal Audits
- Process Control

Key Changes

Structure

Kaizen Consulting
www.kaizengoal.co.nz

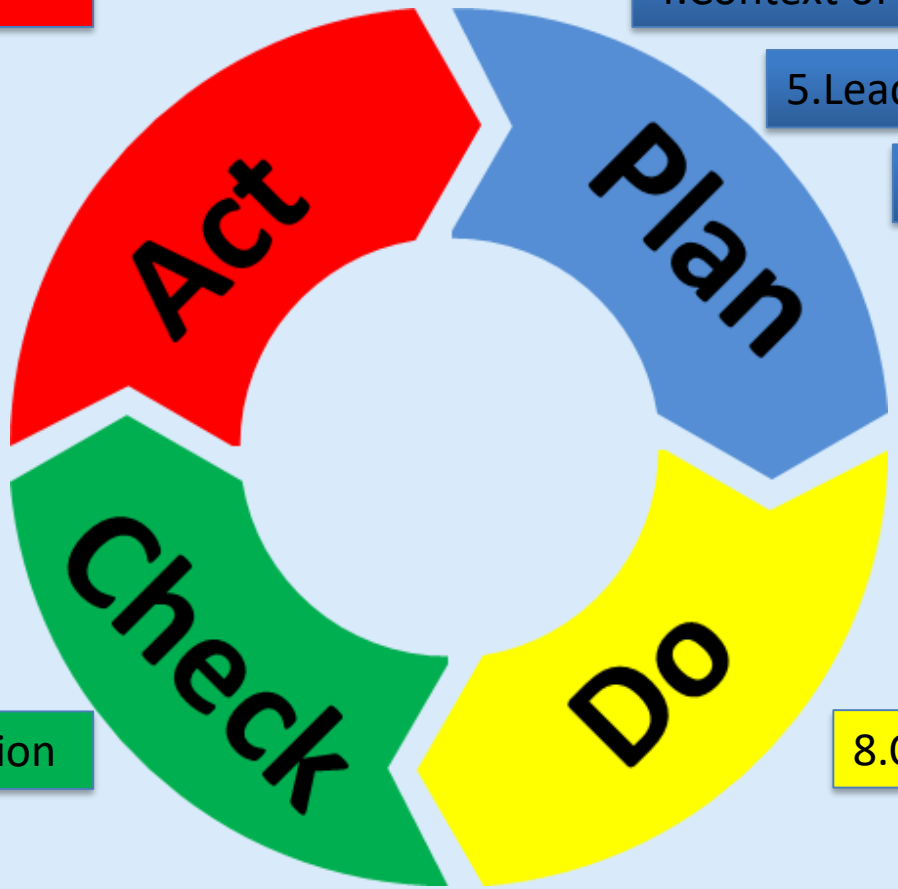
10.Improvement

4.Context of the organisation

5.Leadership

6.Planning

7.Support



9.Performance Evaluation

8.Operations

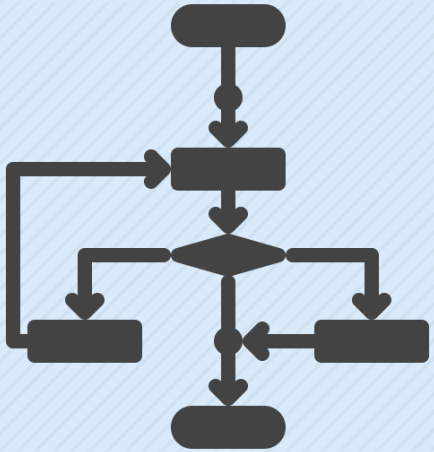
Key Changes

Process Approach

Kaizen Consulting
www.kaizengoal.co.nz

- The interaction between controlled processes make up your quality management system.
- Management strategy to achieve consistent and predictable results.
- Consideration of processes in terms of requirements
- Improvement of processes based on evaluation of data and information

The process approach was promoted by ISO 9001:2008 and is now a requirement in its own right, which sets out the specific requirements for the adoption of a process approach.



Key Changes

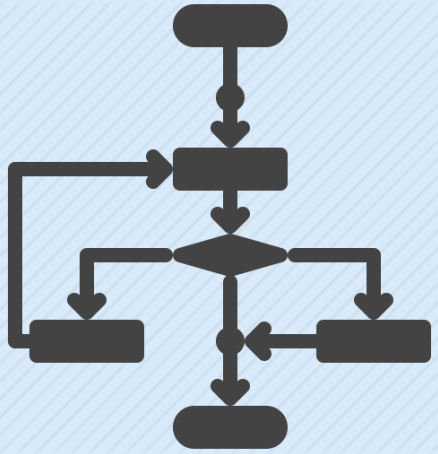
Process Approach

Kaizen Consulting

www.kaizengoal.co.nz

KEY BENEFITS:

- ☑ Ability to identify & focus on critical processes
- ☑ Achievement of consistent and predictable outcome
- ☑ Reduction of cross-functional barriers.
- ☑ Increased effectiveness of process management



Key Changes

Context of Organisation

Kaizen Consulting

www.kaizengoal.co.nz

INTERESTED PARTIES:

- Persons or organisations that can affect or be affected by a decision or activity that your company does. i.e customers, supplier, staff

- You need to have process in place to monitor and review the information about your interested parties and their requirements

- You will need to develop a methodology to understand the needs and expectations of all interested parties.

Key Changes

Context of Organisation

Kaizen Consulting
www.kaizengoal.co.nz

LIST OF INTERESTED PARTIES:

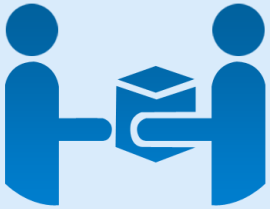
Employees

Stakeholders

End Users

Customers

Suppliers



Regulators

Local Community

Union

(Sample) Interested party	Internal/ External Impact	Objectives	Needs and expectations	Power and Interests Rank	Requirement of QMS from Interested Parties	Related aspect, product/service, process or activity	Responsible person
Customer	External	Achieve Revenue targets. Retain contract. Increase repeat orders.	The consistency of Quality, Competitive price and delivery of products and services	Manage closely	Products and services specifications for design, manufacture, delivery, support, documentation.	Customer Surveys, Customer CARs	Sales & Marketing Manager

Key Changes

Context of Organisation

Kaizen Consulting
www.kaizengoal.co.nz

INTERNAL AND EXTERNAL ISSUES

Your organization is now required to identify and assess all internal and external issues that could impact upon your quality management system's ability to deliver its intended results.

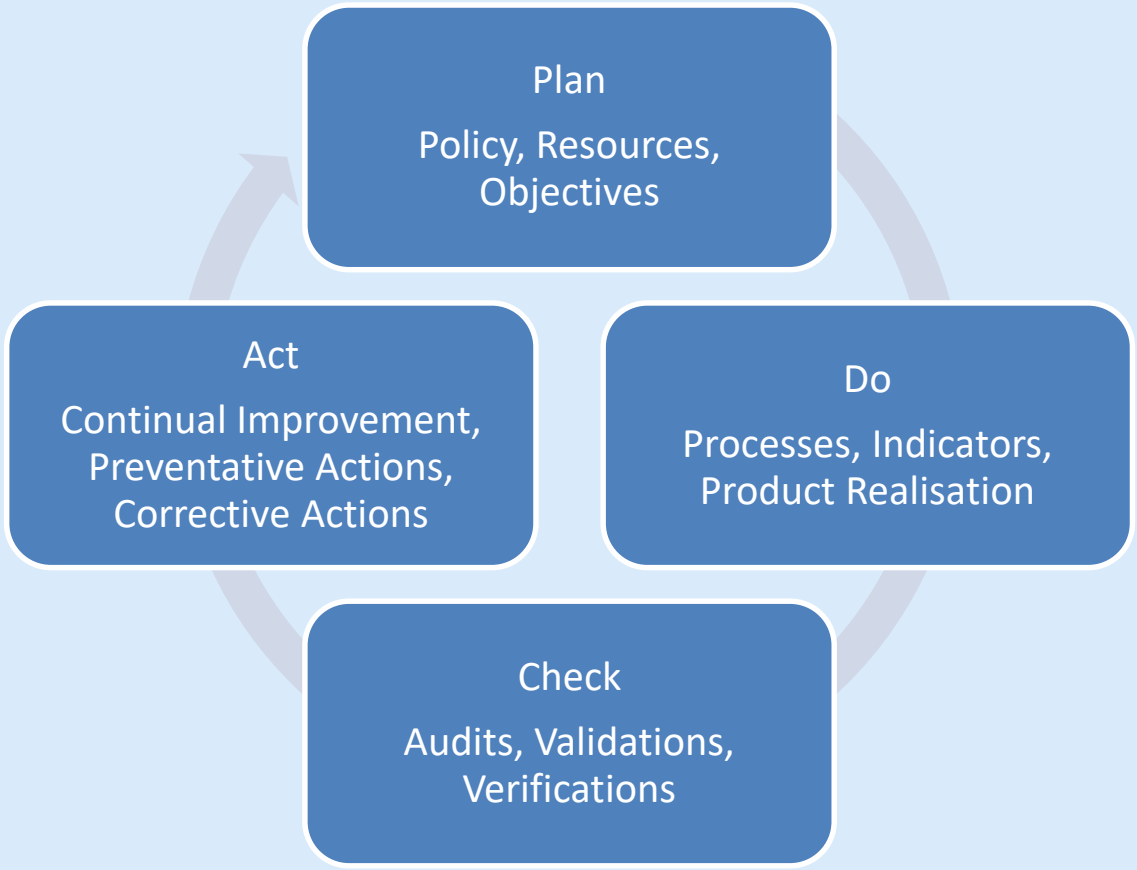
Key Changes

Scope of the QMS

Kaizen Consulting
www.kaizengoal.co.nz

- When determining the scope, the requirement of the interested parties are considered.

- The scope of quality management system should be determined in consideration to your organisation's context.



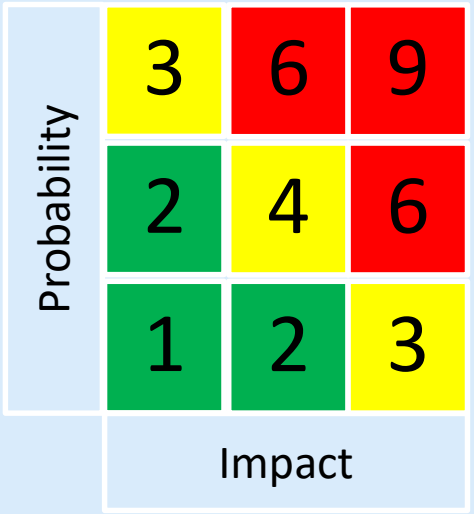
Key Changes

Risks & Opportunities

Kaizen Consulting
www.kaizengoal.co.nz

- Determine, consider and, where necessary, take action to address any risks or opportunities that might impact your quality management system's ability to deliver conformance, or which might adversely impact customer satisfaction.

- We recommend, managing your risks based on likelihood and consequences



Risk ID	Source	Description	Impact	Probability	Significance	Actions	Resp.	Resources	Deadline	Eval. Date	Eval. comment	Current Status
0028	CAR	Emerging number of paint issues	3	3	9	Review, retrain and audit the inspection standard	Prod. Mgr	Supervisor, team leader, quality auditor	30/07/17	25/08/17	Inspection criteria updated. Quality has improved.	Evaluated & Closed

Key Changes

Products & Services

Kaizen Consulting
www.kaizengoal.co.nz

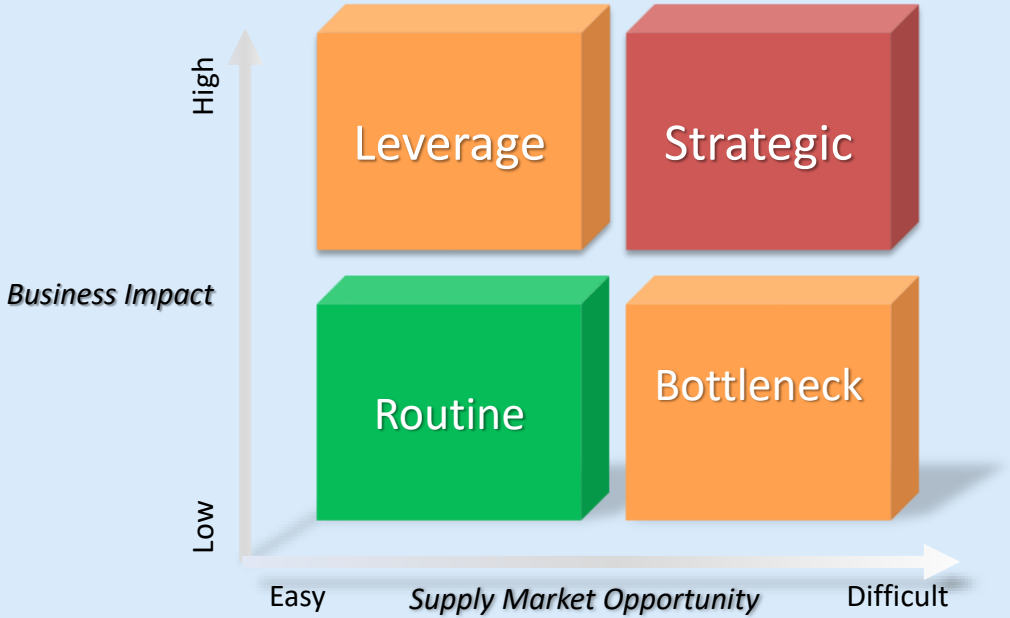
- The term ‘products’ is being replaced by ‘products and services’.
- Reinforces the idea that quality management systems are applicable to all types of business and not just to manufacturing or supplying products.
- Focus on consistently providing products and services that meet customer and the requirement that is expected from your organisation is maintained.
- Ensuring that the organisation has the ability to meet the defined requirements and substantiate the claims for the products and services offer.

Key Changes

Control of Externally Provided Products & Services

Kaizen Consulting
www.kaizengoal.co.nz

- ISO 9001:2008 Clause 7.4 – Purchasing has been replaced with clause 8.4 'Control of externally provided products and services'.
- This clause addresses all types of external provision, purchasing from a supplier, or through the outsourcing of processes.
- Your organisation is now required to take a risk-based approach to determine the type and extent of controls that are appropriate for each external provider and all outsourced processes.



Key Changes

Evidence-based Decision Making

Kaizen Consulting

www.kaizengoal.co.nz

KEY BENEFITS:

- Decisions based on the analysis and evaluation of the KPIs, data and information.
- Ability to achieve objectives
- Easier Process Evaluation
- Ability to demonstrate the effectiveness

ACTIONS:

- Determine, measure and monitor KPIs
- Make data available (Exception Reporting)
- Reduction of cross-functional barriers.
- Ensure people are competent on data analysis

Key Changes

Documented Information

Kaizen Consulting
www.kaizengoal.co.nz

- Requirements for a documented quality manual, documented procedures and records have been removed and replaced with the term ‘Documented Information’.
- “Documented Information” is considered the information your organisation is required to control, retain and maintain.
- Meaningful data that requires to be documented. i.e Quality Policy, Quality Objectives, QMS
- Documented Information can be in any format

Key Changes

Terminology

Kaizen Consulting

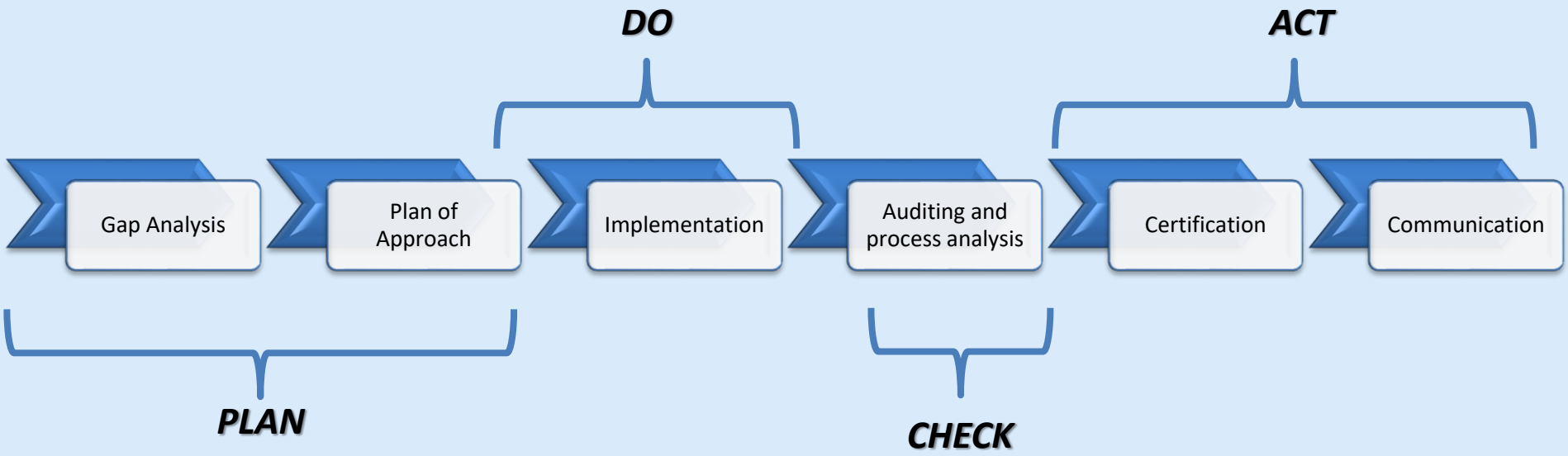
www.kaizengoal.co.nz

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Documentation, quality manual, documented procedures, records, instructions	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider
(Term not used)	Leadership
(Term not used)	Risk

Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Prepare a comprehensive plan for your transition to ISO 9001:2015

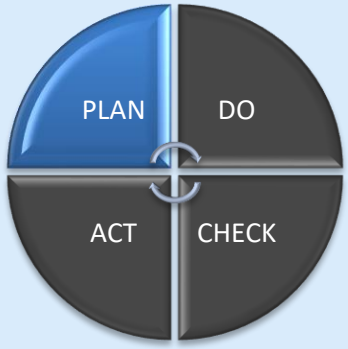


Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis
Learn & Engage → Plan of Approach → Implementation → Auditing and process analysis → Certification → Communication

- Purchase a copy of the ISO 9001:2015 Standard
- Review the Standard and make note of the changes in requirements
- Develop a cross-functional or multi-disciplinary team (including Top Management) to plan out the transition/implementation.
- Identify key milestone
- Conduct a Gap Analysis to identify areas of focus

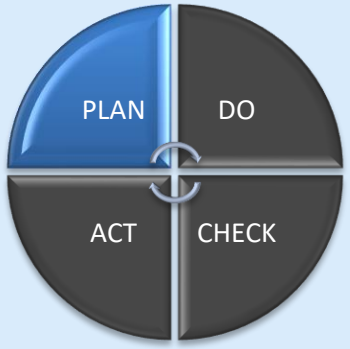


Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis
Learn & Engage → **Plan of Approach** → Implementation → Auditing and process analysis → Certification → Communication

- Review of any documents and records that are unnecessarily, or have become obsolete
- Focus on the documents and records required by the Standard, and those specific to your organisation, to operate and maintain the QMS effectively and efficiently.
- Identify gaps for new processes (e.g Risks & Opportunities)

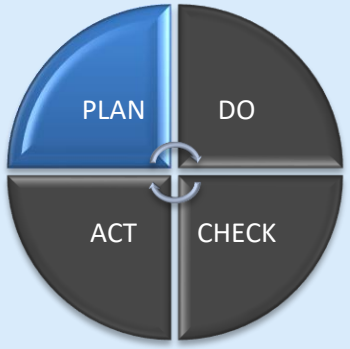


Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis
Learn & Engage → **Plan of Approach** → Implementation → Auditing and process analysis → Certification → Communication

- Perform detailed management review of the implementation plan. This is the best method to ensure that Top Management is engaged and aware of the transition / implementation process.
- Process Owners need to understand their obligations to managing their defined processes and associated indicators.
- Internal Governance teams such as Internal Auditors need to ensure that they understand specific requirements around context, leadership and performance.



Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis Learn & Engage → Plan of Approach → **Implementation** → Auditing and process analysis → Certification → Communication

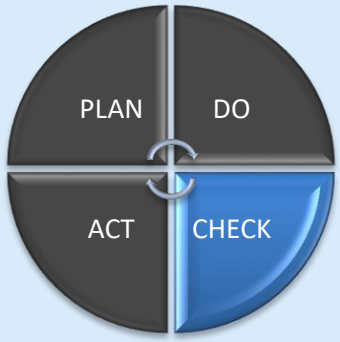
- In-depth analysis of individual gaps in the QMS, deficiencies and processes involved.
- Focus effort on key processes (e.g Review the requirements of Interested Parties, Management of Risks & Opportunities)
- Define Interested Parties and their impact on the business.
- Define the organisation's provided "Products and Services" in the QMS.
- Archive all obsolete documents, records, manuals,…
- Revise the current Quality Management System and Quality Policy to comply with ISO 9001:2015 Standard

Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis Learn & Engage → Plan of Approach → Implementation → **Auditing and process analysis** → Certification → Communication

- Evaluation of the Gap Analysis to check the effectiveness.
- Perform full-system internal audit to verify implementation and Critical Processes.
- Take action(if needed) to address implementation problems and improve the system

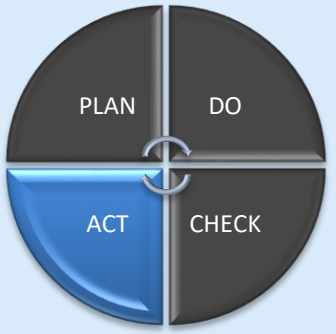


Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis Learn & Engage → Plan of Approach → Implementation → Auditing and process analysis → **Certification** → Communication

- [x] All gaps are closed.
- [x] Organisation's Quality Management System complies with the new standard.
- [x] Management are clear on their responsibilities around the ISO Standard.
- [x] Staff are competent on internal auditing to the new standard.
- [x] An effective internal auditing system is in place that shows positive trends in reducing specific quality defects.
- [x] Get certified by a certification audit body

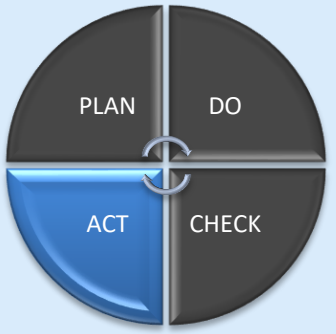


Transition to ISO 9001:2015

Kaizen Consulting
www.kaizengoal.co.nz

Gap Analysis
Learn & Engage → Plan of Approach → Implementation → Auditing and process analysis → Certification → **Communication**

- Communicate the upgrade of your certification to your Interested Parties such as: customers, suppliers, employees, union, stakeholders,….
- Demonstrate your gains and tangible outcomes to Top Management
- Continue the journey of continuous improvement



Transition is an opportunity

Kaizen Consulting
www.kaizengoal.co.nz

1) Take a fresh look at the QMS

2) Review effectiveness of the current controls set

3) More involvement from leadership

4) Treat Key Changes as Opportunity for Improvements

5) Embed management of Risks & Opportunities in your BAU

Questions

Kaizen Consulting

www.kaizengoal.co.nz