ISO 9001:2015 Essentials

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Welcome to 'Introduction to ISO 9001:2015' and thanks for taking this course!

Have your copy of ISO 9001:2015 handy – we'll be referring to it throughout the course.

Print off your PDF notebook and follow along. All of the slides in the videos are in it with room to make notes..

E-mail your name as you would like to see it on your certificate – Jim@SimplifyISO.com. We will create your certificate and send you an electronic copy. Send us your mailing address if you want the original hard copy.

You can contact me at: Jim@SimplifyISO.com or text/phone 519-859-4574 in Canada
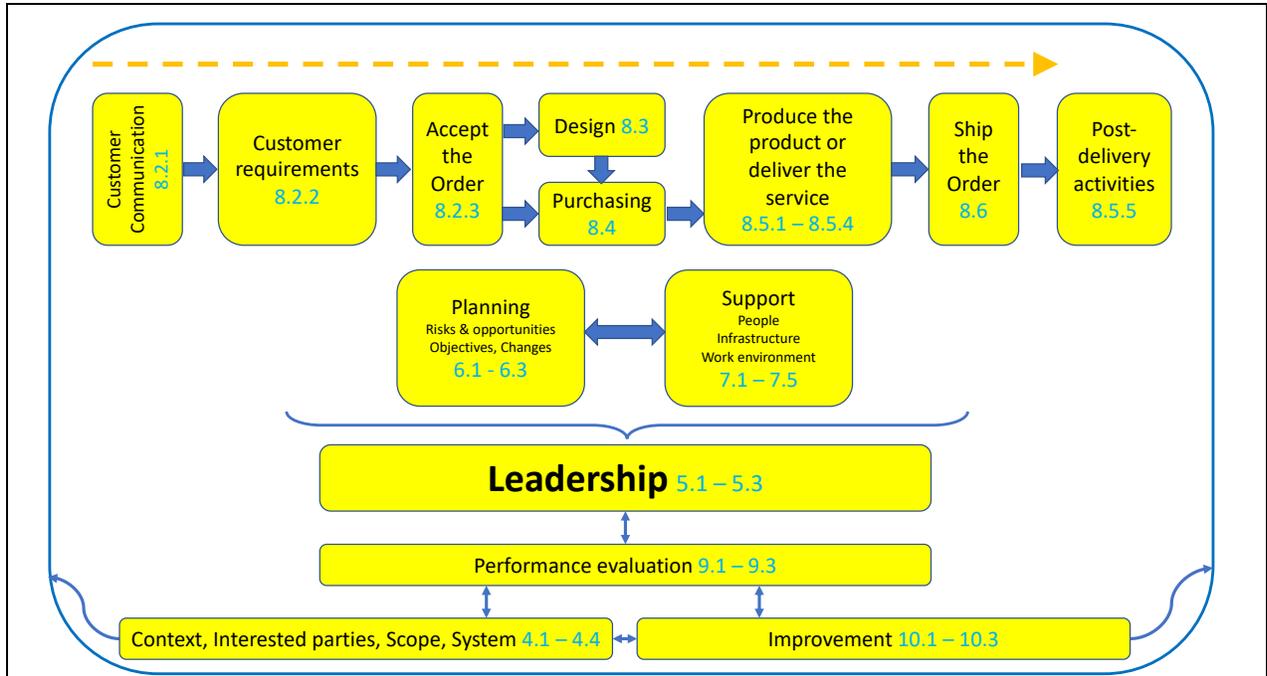
This is the Table of Contents for ISO 9001:2015
Clauses 1, 2 and 3 are general 'Standards information' and are not audited by your 'Certification Body' or 'Registrar'.

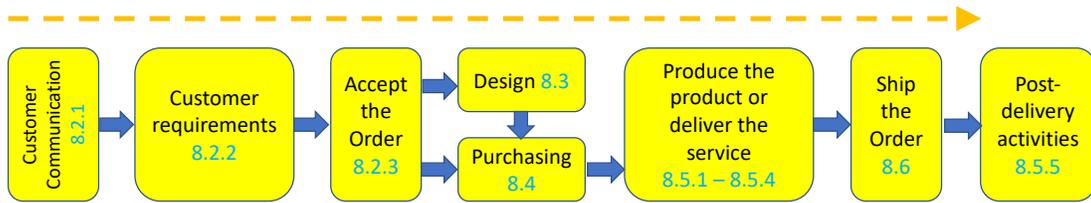In this course, you'll see details on **clauses 4 through 10**.

Notes:

'Terms and definitions' are found in a separate Standard: ISO 9000:2015. There are other Standards in the Quality family such as ISO 9004:2015 (Sustain success).

Customer Communication 8.2.1	Customer requirements 8.2.2	Accept the Order 8.2.3	Design 8.3	Produce the product or deliver the service 8.5.1 – 8.5.4	Ship the Order 8.6	Post-delivery activities 8.5.5
			Purchasing 8.4			

Clause 8.1 is a general clause that talks about 'Planning' and 'Control'

There are requirements in this
clause that will help you get
organized.

Describe what your organization does to meet this requirement:

Customer Communication 8.2.1
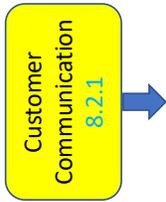
Clause **8.2.1** explains the requirements for **customer communication** – you probably have a website, or phone or e-mail. It also talks about customer property and a new twist – 'contingency plans' because of the increased focus on 'risk and opportunities' in this Standard.

Communication with customers has to include:
1. information about products and services;
2. handling customer orders and any changes;
3. getting customer feedback about their experience with you,
4. taking care of customer property;
5. establishing specific requirements for contingency plans in cases where you need them

Describe what your organization does to meet this requirement:
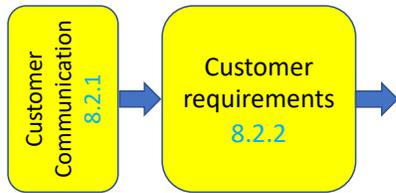
In clause **8.2.2** you're finding out what your customer wants – all the details of the order including 'statutory and regulatory' requirements and any requirements that your organization thinks are necessary for the customer to get what they want.

Describe what your organization does to meet this requirement:

```
Customer          Customer          Accept
Communication     requirements      the
8.2.1             8.2.2             Order
                                    8.2.3
```

8.2.3 Review your organization's capacity to see if you can handle the order, as opposed to saying, "Yay!, We got the order…Now let's figure out how to deliver it!". This includes both delivery and post-delivery (also see 8.5.5) activities like training, installation, servicing or warranty work if it's a product.

Describe what your organization does to meet this requirement:

8.3 – **Design and development of Products and services**

If your customer has an idea but no drawings, you will have to design it for them. This would apply to services, too. A consulting company might 'design' a project. It's not common, but it could happen.

Describe what your organization does to meet this requirement:

8.3.1 – Have a 'design process' in place rather than 'just start drawing'. This is more efficient and reduces errors.

Describe what your organization does to meet this requirement:

8.3.2 Design and development planning – think of Deming's 'Plan-Do-Check-Act' model. Start with a plan.

Describe what your organization does to meet this requirement:

8.3.3 Design inputs – this follows that 'Process Approach' idea: **Input > Process > Output**

There are 5 (a…e) requirements here plus a requirement to **'retain documented information'** about the inputs. This means 'record the inputs'.

You decide how – there's no 'best practice' for design input records.

Describe what your organization does to meet this requirement:

8.3.4 Control of the design and development process – 6 (a…f)
Requirements here **include four records:**
1. reviews,
2. verification activities,
3. validation activities and
4. corrective actions needed from the verification and validation activities

Describe what your organization does to meet this requirement:

8.3.5 Design and development outputs
(drawings, usually), and they have to meet the input requirements and they have to be 'usable'. Might include an inspection and test plan (ITP) for the production folks and any safety concerns for the workers or the customer.

Describe what your organization does to meet this requirement:

8.3.6 Changes
They must be managed, and risks considered.

Describe what your organization does to meet this requirement:

8.4 Control of externally provided process, products and services – usually known as 'Purchasing'

8.4.1 General
Refers to any processes, products and services you purchase or acquire to fulfil your customers' requirements.

Includes selection criteria for suppliers – how do we choose them?

There's another section later (8.5.3) that talks about things provided by your customer and external providers.

Describe what your organization does to meet this requirement:

8.4.2
Control of externally provided processes, products and services.
There are ways to make sure that what you get is what you wanted, other than just inspecting it when it arrives or the service is delivered – see a)...d). This can also be another division of your own company.

Describe what your organization does to meet this requirement:
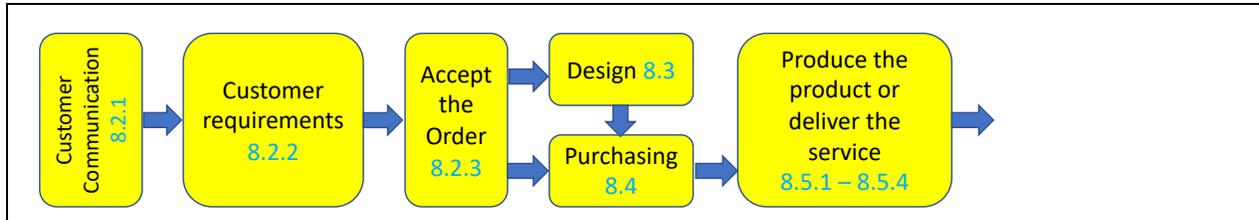
8.4.3 Information for external providers ('Suppliers')

Normally done in a 'request for quote' or purchase order to your suppliers. See (a...f) for details of what needs to be in there.

Review suppliers and report on their performance.

This includes 'outsourcing' products, processes or services.

Describe what your organization does to meet this requirement:

8.5.1 – Control of Production and service delivery

This section starts with a list of things to do to make sure production of your goods or services goes well. The Standard calls this **'controlled conditions'**

When producing a product or delivering a service:
   a) Product details or 2: results to be achieved if it's a service
   b) In process monitoring and testing equipment
   c) Performing the tests
   d) Having the right infrastructure and work environment
   e) Having competent people with the appropriate certification
   f) 'Special Process' control where testing cannot reveal issues – activities like welding, painting, powder coating, chrome plating, soldering, buffing, etc. where the problem only shows up after the product is in use
   g) Actions to prevent 'human error'
   h) Control of releasing the product, delivering the product and any relevant 'post-delivery' activities like training, installation, servicing or repairs or warranty

Describe what your organization does to meet these requirements:

a)

b)

c)

d)

e)

f)

g)

h)

8.5.2 Identification and traceability
Make sure nothing gets mixed up!

Clients may have some specific requirements for part identification or data file identification.

Examples: serial numbers, heat treat numbers, data file identification and naming conventions

Pharmaceuticals – lot numbers, expiration dates

Describe what your organization does to meet this requirement:

8.5.3 Property belonging to customers or external providers

Keep track of all customer property, including intellectual property.

Let them know if there any issues with the property that they sent

Take care of it and if it's not suitable, let them know – document it, too.

Describe what your organization does to meet this requirement:

8.5.4 Preservation
Protect parts, subassemblies during production, packaging and shipping.

Same for data and intellectual property

Keep parts, sub-assemblies and products in a way that they conform until they're ready to pack and ship.

Describe what your organization does to meet this requirement:

8.5.5 Postdelivery activities – more on this in the next section

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8.5.6 Change control

If the order changes (8.2.4) this might cause a change in design (8.3.6).

A design change could affect purchasing (8.4).

A new part could change the production line (8.5.1) and the way it's handled and packaged (8.5.4).

It might change the way inspections are done, too (8.5.1 c).

That's why **changes need to be 'managed'.**

Describe what your organization does to meet these requirements for each area of 'change':

8.2.4 – Change to a customer order

8.3.6 – Design change

8.4 – Externally supplied processes, products and services (Purchasing)

8.5.1 – Production

8.5.1 c) - Inspections

8.5.4 – Packaging
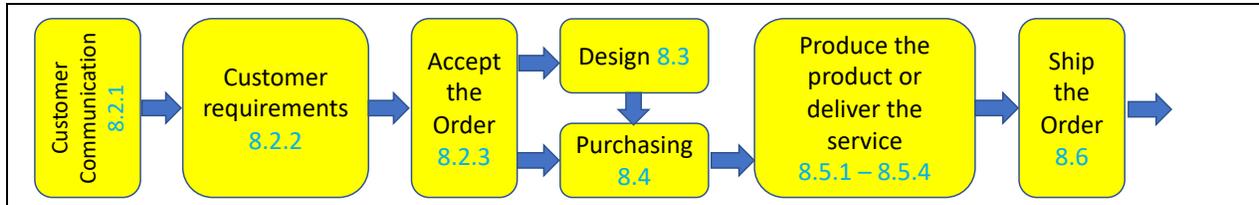
8.6 Release of Products and services

You need to ensure that the order conforms to requirements before it go   ents have been made to 'ship anyway'.

There's also a requirement here to be able to identify who said the order was OK to ship or the service delivered was OK.

Describe what your organization does to meet this requirement:

8.7 Control of non-conforming products or services

Remember the **Input -> Process -> Output** model?

Any time something goes wrong, it needs to be managed.

The idea, of course, is to make sure the customer never gets an off-spec product or service.

Documentation and corrective actions are required when needed.

Non-conformance: non-fulfilment of a requirement (ISO 9000:2015, 3.6.9)

Could be a customer requirement, a health and safety requirement, an environmental requirement – any requirement that you've committed to meeting.

Describe what your organization does to meet this requirement:

8.5.5 Post-delivery activities

Anything that you provide after delivery is normally written into the contract and decided ahead of time. In any case, these activities must meet legal and regulatory requirements, risks need to be addressed, life cycle (if it's a product) is important, customer requirements (of course!) and customer feedback is essential on how the whole order went together.

Describe what your organization does to meet this requirement:

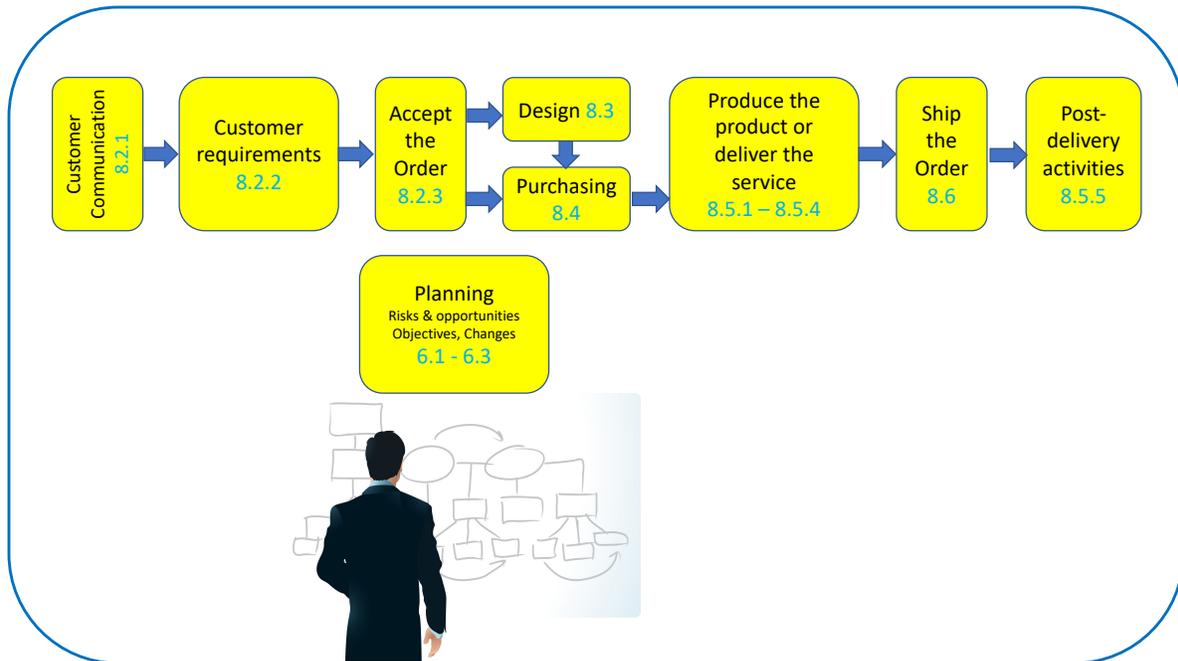The quiz for Clause 8 is on the next page…

Clause 8 Quiz
Open book - use your ISO 9001:2015 Standard. ***The solutions are at the end of the workbook.***

1. Customer communication includes: (**choose all that apply**)
   a. Product and service information
   b. Contract and order handling (including complaints)
   c. Special offers and financing options
   d. Changes to orders
   e. Information related to customer property

2. When deciding whether to accept an order from a customer, an organization must consider:
   a. Customer requirements
   b. Competitors' pricing and quality
   c. Requirements not stated by the customer but necessary for the intended use
   d. Legal requirements that apply to the product or service
   e. a, c and d

3. The organization has to have a record (retain documented information) on the results of the review of the order and any new) customer requirements.
   a. True
   b. False

4. Design and development controls must include (**choose all that apply**):
   a. The end result that the customer wants
   b. Information from design reviews (records of reviews)
   c. Verification activities
   d. Validation activities
   e. Documented sign-off from the customer at each step of the design process

5. When purchasing from a supplier, an organization must consider:
   a. The supplier's price and nothing else
   b. How the parts are packaged – purchase recyclable packaging only
   c. The amount of recycled materials in the part
   d. The ability of the supplier to provide the process, products and services that conform to requirements
   e. The country of origin

6. Control of production and service provision has to include (**choose all that apply**):
   a. Clear information about the product or service
   b. The name of the employees who will make the product or deliver the service
   c. Monitoring and measuring equipment
   d. Work schedule including coffee breaks
   e. Actions to prevent human error

7. Property belonging to customers needs to be (**choose all that apply**):
   a. Identified

    b. Stored in a way to keep it in usable condition
    c. Assessed for suitability before use
    d. Always entered into our inventory system for inventory control
    e. Discarded if unsuitable – no mention of it to the customer

8. Organizations who do post-delivery activities need to consider:
    a. Statutory and regulatory requirements
    b. How the product is going to be used and how long it will likely last
    c. Competitors' similar products and pricing
    d. Customer requirements and customer feedback
    e. a, b and d

9. Release of Products and services documentation needs to include:
    a. Evidence that customer requirements have been met
    b. The names of the suppliers for all the parts in the assembly of the order
    c. The brand of packaging used and its origin
    d. The name of the person authorizing the release
    e. All of the above
    f. a and d

10. When controlling non-conforming products or services, the organization needs to document information about (**choose all that apply**):
    a. A description of the problem
    b. Actions taken related to the problem
    c. Why the problem happened
    d. Concessions obtained (e.g. money paid back to the customer or credit given)
    e. Who was authorized to take action related to the non-conformity

Answers are in the *'Solutions'* section at the end of the workbook

Sections 6 & 7 – Planning and Resources

Customer Communication 8.2.1 → Customer requirements 8.2.2 → Accept the Order 8.2.3 → Design 8.3 → Purchasing 8.4 → Produce the product or deliver the service 8.5.1 – 8.5.4 → Ship the Order 8.6 → Post-delivery activities 8.5.5

Planning
Risks & opportunities
Objectives, Changes
6.1 - 6.3

Planning
Risks & opportunities
Objectives, Changes
6.1 - 6.3

6.1 Risks and Opportunities

6.1.1 – Actions to address risks and opportunities

When you identify a risky activity that could cause a problem, this creates an opportunity to improve your system. Every risk contains an opportunity.

Enhance the good aspects of your system and improve the weak areas to avoid problems.

6.1.2 Actions to address risks and opportunities

This is the section where you create the plans to manage the risks you've identified. Some people use a spreadsheet, pop-ups on flowcharts, grids, tables – all kinds of formats will work.

ISO 31000 can be helpful for developing an approach to risk management.

By the way, you're required to assess the effectiveness of these actions in 9.1.3 e) (Performance Evaluation) and have management review the effectiveness of these activities in 9.3.2 e), Management Review.

Describe what your organization does to meet this requirement:

Planning
Risks & opportunities
Objectives, Changes
6.1 - 6.3

6.2 Quality Objectives and Planning to meet them

Objectives need to be set at *relevant* levels and functions in the organization.

6.2.2 Action plans to reach objectives:

a) What activities will you do?
b) What resources will you need?
c) Who will be responsible?
d) What is the time frame?
e) How will the results be evaluated and reported?

Start with any Key Performance Indicators you have in place already. People will already know them.

Weave the measurements into your day-to-day activities. Communicate them (see 7.3 Awareness) and make everyone aware (see 7.4 Communication).

Describe what your organization does to meet this requirement:

Planning
Risks & opportunities
Objectives, Changes
6.1 - 6.3

6.3 Planning of Changes

Changes to the management system need to be managed so there are no nasty surprised or unwanted results.

Things can Some sources of the need for change to your management system:

Competitors
Interested Parties
Laws
Customers (Internal and External)
Exchange rate
Non-conformances from Audits (Internal and External)
Management Review
Customer feedback

Use your risk management method when implementing the changes to avoid any 'unwanted results'.

Describe what your organization does to meet this requirement:

The quiz for Clauses 6 and 7 is at the end of Clause 7

Clause 7 − Resources, Competence, Awareness, Communication and Documented Information

7.1 Resources

7.1.2 People
There needs to be enough of them and they need to be competent (7.2 – Competency)

7.1.3 Infrastructure
Buildings, IT, equipment – everything you need to 'make it happen'. A 'Preventive Maintenance' program helps here.

7.1.4 Work environment
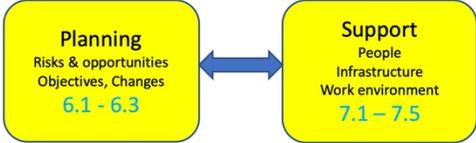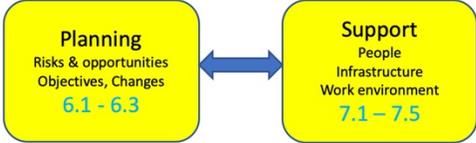This is everything other than the infrastructure that impacts people at work – temperature, noise, dust, vibrations on the physical side. Beyond the basics there are the social and psychological elements: non-discriminatory, non-confrontational, supportive, non-threatening, burnout protective as examples. These are itemized in the 'Notes' section. People who have what they need are more productive.

7.1.5 Monitoring and Measurement Resources
This is likely already in place as a 'calibration program'. You need to have measuring equipment capable of measuring to the tolerance your customers want and you need to keep it calibrated.

7.1.6 Organizational Knowledge
This refers to information about how you run as an organization, but does not refer to work instructions or procedures. It generally comes from meetings, experience, lessons learned from success and failure, improvements to processes and other internal sources. External sources would include standards, customers, suppliers and others. Check out the 'Notes' for this area.

By capturing organizational knowledge, the impact of a key employee leaving is lowered. Building the knowledge base can be a valuable asset for some organizations.

Describe what your organization does to meet these requirements:

7.2 Competence
People '…working under the organization's control…' need to be competent. This means subcontractors, too.

7.3 Awareness
People '…working under the organization's control…' need to be aware of the Quality Policy and any relevant objectives. This means subcontractors, too.

7.4 Communication
Like so many other things, if this is 'planned' it will go much better!

7.5 Documented information.
Some of it is 'maintained' (procedures, work instructions, operating information, policies, objectives, etc - things that change)

Some is 'retained' – these are usually called records and have to be protected against unauthorized changes.

Creating, modifying: check with the people who run your system to see how much you can do. Most organizations create much more documentation than they need. They also tend to make creating, identifying and modifying documents much more complicated than it needs to be.

Describe what your organization does to meet these requirements:

Clause 6 & 7 Quiz
(5 questions from Clause 6 and 5 questions from clause 7)

Open book - use your ISO 9001:2015 Standard. ***The solutions are at the end of the workbook.***

Clause 6:

1. Risks are determined so that the organization (**choose all that apply**):
   a. Has more confidence that they can achieve the results that they want
   b. Can get an ISO 9001 certificate
   c. Make improvements to the management system
   d. Enhance the things that are working properly
   e. None of the above

2. Quality Objectives must be (**choose all that apply**):
   a. Measurable
   b. Monitored
   c. Updated
   d. Communicated
   e. Maintained as documented Information

3. Quality Objectives could be met with an 'action plan' that includes (**choose all that apply**):
   a. Actions that the plan intends to carry out
   b. Resources needed for the action plan
   c. A person or people responsible for the plan
   d. A timeline for completion
   e. Unlimited budget for staff parties to celebrate milestones

4. When managing changes to the system, changes have to be planned, including:
   a. Why the change is being made
   b. The possible consequences of the changes
   c. Availability of resources including people and time
   d. Changes to the organizational structure – changes in responsibilities
   e. All of the above

5. If risks are identified, no problems will ever occur
   a. True
   b. False

Clause 7:

6. Resources for the operation of an organization include, but are not limited to:
   a. People
   b. Infrastructure
   c. Work environment
   d. a), b) and c)

e. None of the above – resources are things like lumber, water and ore

7. Provision of monitoring and measuring resources must include (**choose all that apply**):
   a. Suitable equipment to take appropriate measurements
   b. The name of all employees who will take the measurements
   c. Calibration activities to ensure that the equipment will perform properly
   d. Identification of the status of the measurement devices (in or out of calibration)
   e. Documentation of the suitability of measuring devices

8. In order to be sure people are competent, the organization has to (**choose all that apply**):
   a. Determine what skills people need that affect the performance of the quality management system
   b. Make sure people have suitable experience, education and training
   c. Assess the effectiveness of any actions taken to improve people's competence
   d. Keep records (retain documented information) of competence
   e. Fire anyone who isn't competent

9. In order to be sure that all persons working under an organization's control are suitably 'aware', the organization only has to give each person a copy of their Quality Policy
   a. True
   b. False

10. Management System documentation may include, but is not limited to (**choose all that apply**):

    a. Records of employee competence
    b. Processes the organization thinks they need to operate effectively
    c. Methods to create and update documents (policies, procedures, forms, etc.)
    d. The name of the person(s) who reviewed and approved the documents in 'c)' above
    e. A means to make sure that everyone has access to the information they need when they need it

Answers are in the *'Solutions'* section at the end of the workbook

Clause 5 – Leadership
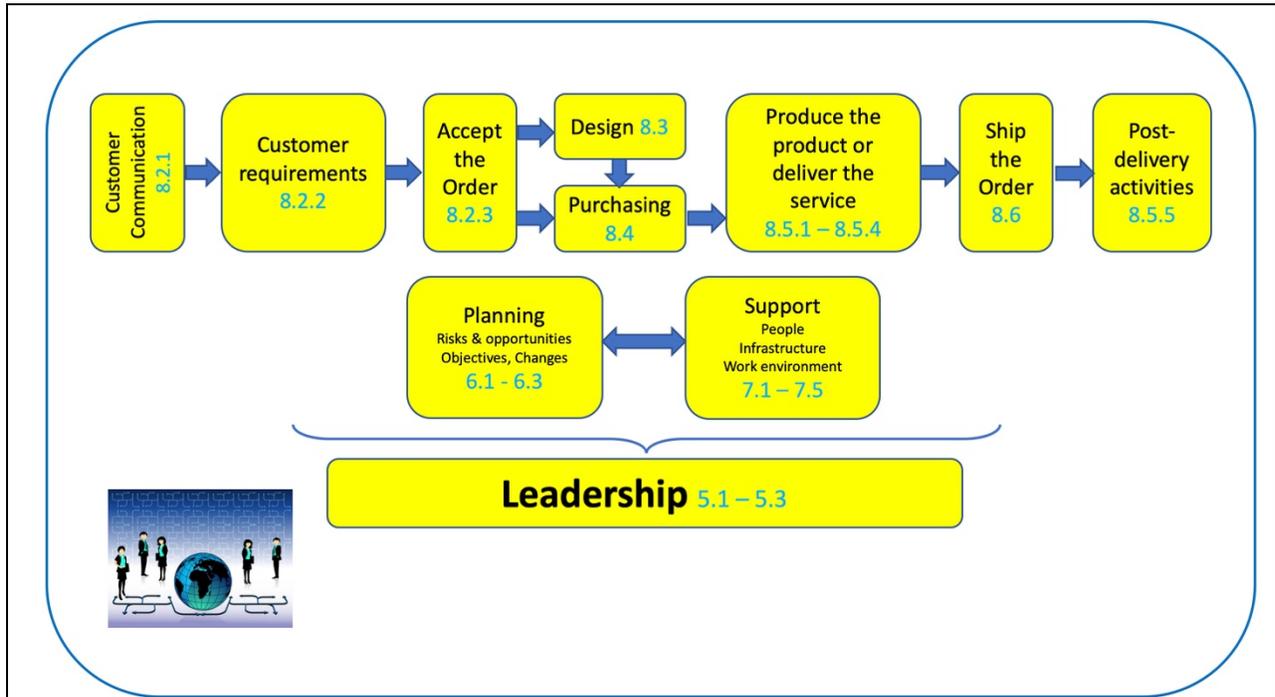
5 Leadership

This section sets out the requirements for Top Management, the Policy and Organizational Structure. This block affects or 'supports' the rest of the system.

Leadership is at the core of ISO 9001, 14001, 50001 and 45001.

5.1.1   Leadership and Commitment

These **10 requirements** are designed to get Management involved in the system:

a)   Accountability for the effectiveness of the Management System can be demonstrated by attending Management Review (9.3) at the very minimum. Other ways to demonstrate it might be to have information sessions on how well things are going. Many organizations do this, and this can be evidence for this point. Daily, weekly, monthly, quarterly, semi-annual or annual meetings all contribute to meeting this requirement.

b)   Policy (5.2) and objectives (6.2) are easy to prove, and the objectives need a 5-part (at least) action plan (6.2.2).

c)   This means weaving the requirements of ISO 9001 into the way you do business, not add it on as 'extra' work. Make ISO 'how we do business' so there's no one saying, "I've done my days' work, now I have to do my ISO stuff".

d) Promote the use of 'the process approach' and 'risk-based thinking'. Flowcharts and a risk table will show that these ideas have been promoted.

e) Resources are a given. They also get reviewed in Management Review (9.3). You have to have adequate resources to meet customer requirements AND manage the system – internal audits, corrective actions, tracking performance, management review and the rest of the ISO 9001 requirements.

f) This communication can be done many ways – town hall meetings, tailgate meetings, huddles, formal and informal communications, banners, monitor messages, text messages on company phones…and anything else people need to meet customer needs and expectations.

g) Ensure the system is producing the expected results. Performance assessment (Clause 9) will demonstrate this as well as Management Review (9) and other feedback mechanisms – Internal audits, external audits, customer audits, Management Review, metrics. Regulatory Body visits will reveal how well the system is working, too.

h) Management has to **get people on board** supporting the management system. This is a matter of Leadership style. Ask employees to rate management on this one and tell management the results.

i) Promoting Improvement is how ISO pays a dividend on the investment. The three ISO 'pillars' are 1. Customer Focus, 2. the Process Approach and 3. Continual Improvement.

j) Encouraging and support other levels of management to demonstrate leadership enhances the 'power' of top management.

Describe what your 'Top Management' does to meet these requirements:
a)
b)
c)
d)
e)
f)
g)
h)
i)
j)

Leadership 5.1 – 5.3

5.1.2 – Customer Focus

Top management needs to lead the way to keep the customer in focus. People will treat customers the way they see Management behaving. Management has to 'walk the talk' – a phrase coined by Ken Blanchard.

a) Essential for survival and starts with 8.2.2 determining customer requirements.
b) Then risk assessment needs to be robust – risks need to be identified and managed
c) Make sure that the organization is committed to enhancing customer satisfaction by meeting customer requirements – not just paying lip service.

Maintain the focus on customer satisfaction!

Describe what your organization does to meet these requirements:

Leadership 5.1 – 5.3

5.2 Quality Policy

The policy has to be appropriate to the purpose of your organization – mention what industry you're in at least, and perhaps a bit more detail about your position in that industry

The Policy serves as a framework for the Quality Objectives that you saw in clause 6.2

Has to have a commitment to satisfying applicable requirements – all requirements: customer, legal, regulatory, documentation, association – anything related to an order.

There needs to be a commitment to improving the effectiveness of the Quality Management System. This idea of 'system improvement' appears **11 times** in this Standard.

Make the Policy easy to read and understand. It needs to be 'applied' in your organization and you have to be able to show how this has been done. Make it accessible to Interested Parties.

Describe what your organization does to meet this requirement – locate your Quality Policy

Leadership 5.1 – 5.3

5.3 Organizational roles, responsibilities and authorities

The organizational structure needs to be '…communicated and understood..' by persons working under the control of the organization…

This can be achieved with an organizational chart. You might want to have job descriptions linked to the title box on the org chart. The information has to be kept up to date. This is done with 'document control'.

Specific responsibilities that have to be delegated:
- Someone has to be responsible to make sure the system meets the requirements of ISO 9001
- The processes have to be assessed to see if they're getting the results you're after
- Responsibility has to be assigned to determine Opportunities for Improvement and Top Management has to be made aware of them. Top management also has to be made aware of how well the system is working
- Customer focus needs to be promoted throughout the organization

Make sure that changes are managed to reduce any negative outcomes. Use your flowcharts to avoid any unplanned results.

Leaders need to understand the impact they have on the management system.

**Describe what your organization does to meet this requirement:**

Clause 5 Quiz:

Open book - use your ISO 9001:2015 Standard. ***The solutions are at the end of the workbook.***

1. Top Management shows leadership by (**choose all that apply**):
    a. Making sure the Quality Policy and Quality Objectives are established
    b. Making overtime mandatory
    c. Engaging directing and supporting people to contribute to the effectivenss of the QMS
    d. Finding new customers
    e. Promoting improvement
    f. All of the above

2. Customer focus has to include (**choose all that apply**):
    a. The lowest price
    b. Understanding and meeting customer requirements
    c. Understanding and meeting statutory and regulatory requirements
    d. Fast delivery
    e. Attention to enhancing customer satisfaction

3. The Quality Policy typically includes (**choose all that apply**):
    a. A commitment to continual improvement
    b. Every product and service that the company offers
    c. A history of the organization
    d. Communication to interested parties, as appropriate
    e. Evidence that it is appropriate to the purpose of the organization

4. When organizing and delegating, responsibility is assigned to someone to (**choose all that apply**):
    a. Make sure the management system meets all of the ISO 9001 requirements
    b. Measure whether processes are creating the right results
    c. Find opportunities for improvement of the system
    d. Make 'customer focus' a habit throughout the organization
    e. Control changes to the system

5. As long as everyone knows the Quality Policy, it does ***not*** have to be documented
    a. True
    b. False

Answers are in the ***'Solutions'*** section at the end of the workbook

Clause 9 – Performance evaluation
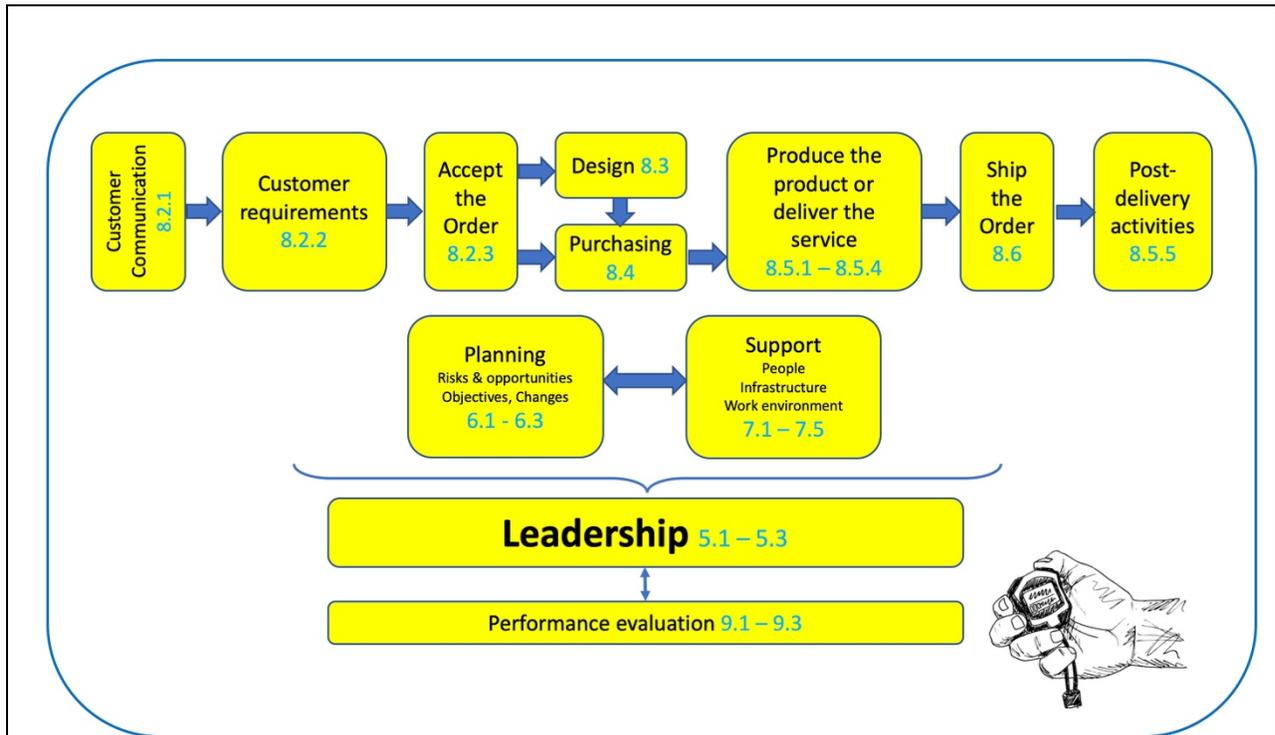
9 Performance Measurement

9.1 – General – a description of measurement requirements:
1. What will you measure?
2. How will you take these measurements?
3. When will you do it?
4. When will you analyze the results, and what happens then?

You want to make sure that you're meeting customer (and other) requirements.

Process Approach:

Input –> Process –> Output

$1---------$10---------$100

Clause 9.1.3 has some specific things to analyze:
a) Conformity of products and services mentioned above – 8.5.1 c)
b) Customer satisfaction – 8.2.1 c), 9.1.2
c) Performance and effectiveness of the Management System – Internal audits, external audits, customer audits, process audits, product (or service) audit, line audit, regulatory body inspections and any other activity that gives you feedback on how well the system

is working (meeting objectives and customer requirements) You can track non-conformances to get a sense of how well the system is working. Do root cause analysis to find out why non-conformances occur and implement corrective actions to prevent recurrence. More about this in Clause 10 'Improvement'. Opportunities For Improvement (OFIs) are helpful, too. Turnaround time is a good measure as well.

d) Effectiveness of planning. This is indicated by how many 'surprises' are occurring. Better planning usually leads to smother operation, fewer non-conformances and happier customers. Make sure you have the right team assembled. Planning leads to smoother workflow and more profit.

e) Effectiveness of actions relating to assessing risk and opportunities (Clause 6.1) – like #4, the better this is, the fewer 'issues' you'll have.

f) Supplier performance – not ALL suppliers, but a cross-section is useful. Keep the good ones, ditch the bad ones if you can. Sometimes a supplier is 'the only game in town' and you have to use them. Some organizations also do an activity called 'supplier development' and try to get their suppliers to perform better. Win-win.
Suppliers can keep you informed about trends in your industry that you might not hear about.

g) Opportunities For Improvement (OFIs). This can be the focus of your internal audits. These appear during audits and inspections. The more, the merrier – improvements, when they are done effectively, lead to higher profit. In the case of the Public service, improvements can lead to 'stay within the budget'.

Describe what your organization does to meet these requirements:

Performance evaluation 9.1 – 9.3

9.2 Internal Audit

9.2.1
Not everyone loves doing them, but they can bring a lot of value to an organization.

You have to have a **schedule** – it needs to consider the importance of processes, changes to your system and results from previous audits.

Auditors have to be **competent**, but you decide what that means – put the 'competence' requirements into your Internal Audit Procedure.

Auditors have to be **'objective'** so that the audit activity produces valid results. They will not want to be auditing their own work – they can audit in their own department, just not their own work.

Ask about our auditing course offerings!

You choose the time frame for audits – just make sure that you audit your entire system annually to make sure it's paying dividends and helping you keep your customers happy. It could be done on any schedule that suits you: all at once, monthly, quarterly, semi-annually, weekly, daily – any interval that will help you to improve your system.

Results are reported to Top Management in an 'audit report'.
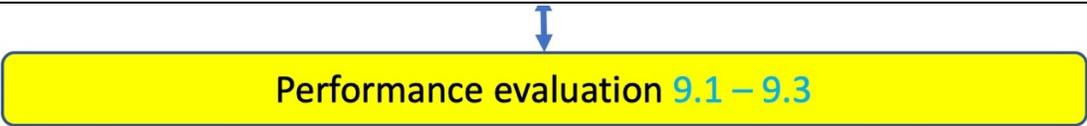
Audit plans need and Objective, a Scope and some Criteria to audit against.
Objectives could include: a production line, quality objectives, ISO 9001.
Scope: over the course of a year, your Registrar will likely want you to audit your entire system.

You'll see a built-in 'audit report' on our platform

Describe what your organization does to meet these requirements:

Performance evaluation 9.1 – 9.3

9.3 Management Review

9.3.1 General – For Management to review the effectiveness of the Management System

Look at Quality Policy (5.2). Internal and External issues (Clause 4.1, Context), Interested Parties (4.2), Minutes from previous reviews.

9.3.2 – Inputs to Management Review

Clause 9.3.2 has some specific things to analyze:
1. Conformity of products and services mentioned above – 8.5.1 c)
2. Customer satisfaction – 8.2.1 c), 9.1.2
3. Performance and effectiveness of the Management System – Internal audits, external audits, customer audits, regulatory body inspections and any other activity that gives you feedback on how well the system is working (meeting objectives and customer requirements)
4. Effectiveness of planning. (shown by non-conformances and corrective actions) This is indicated by how many 'surprises' are occurring. Better planning usually leads to smother operation and fewer non-conformances
5. Effectiveness of actions relating to assessing risk and opportunities – like #4, the better this is, the fewer 'issues' you'll have. Top management is required in clause 5.1.1 d)
6. Supplier performance (external providers) – not ALL suppliers, but a cross-section is useful. Keep the good ones, ditch the bad ones if you can. Sometimes a supplier is 'the only game in town' and you have to use them. Some organizations also do an activity called 'supplier development' and try to get their suppliers to perform better. Win-win.
7. Opportunities For Improvement (OFI). These appear during audits and inspections. The more, the merrier – improvements, when they are done effectively, lead to higher profit. In the case of the Public service, improvements can lead to 'stay within the budget'.

9.3.3 – Outputs from Management Review

This is the documented blueprint for 'next steps' for the organization if they're using ISO as a tool to run their business.

Specific outputs are, at least:
1. Opportunities for Improvement
2. Need for changes to the system

3. An assessment of the adequacy of your resources

Describe what your organization does to meet these requirements – ask to have a look at a past Management Review report or meeting minutes.

The Clause 9 Quiz is next!

ISO 9001:2015 Essentials

Clause 9 Quiz:

Open book - use your ISO 9001:2015 Standard. ***The solutions are at the end of the workbook.***

1. Measurements have to be taken in these areas (**choose all that apply**):
    a. Profitability, employee turnover and environmental performance
    b. The degree of customer satisfaction
    c. The performance and effectiveness of the Quality Management System
    d. The number of new customers per month
    e. The performance of external providers

2. Internal audits have to include (**choose all that apply**):
    a. A plan
    b. Criteria and scope for each audit
    c. Auditors chosen to ensure objectivity
    d. Documented information describing the results of the audit (like and audit report)
    e. Appropriate corrective actions after the audit

3. Management Review inputs include (**choose all that apply**):
    a. Customer satisfaction and feedback
    b. Process performance, conformity of products and delivery of services
    c. A history of the organization
    d. Audit results
    e. Adequacy of resources

4. Management Review outputs include (**choose all that apply**):
    a. Resource requirements
    b. Suggested pay raises based on the system performance
    c. Need for changes to the system
    d. Opportunities for improvements to the system
    e. All of the above

5. As long as everyone has heard about the Management Review, it does ***not*** have to be documented
    a. True
    b. False

Answers are in the ***'Solutions'*** section at the end of the workbook

Clause 10 - Improvement
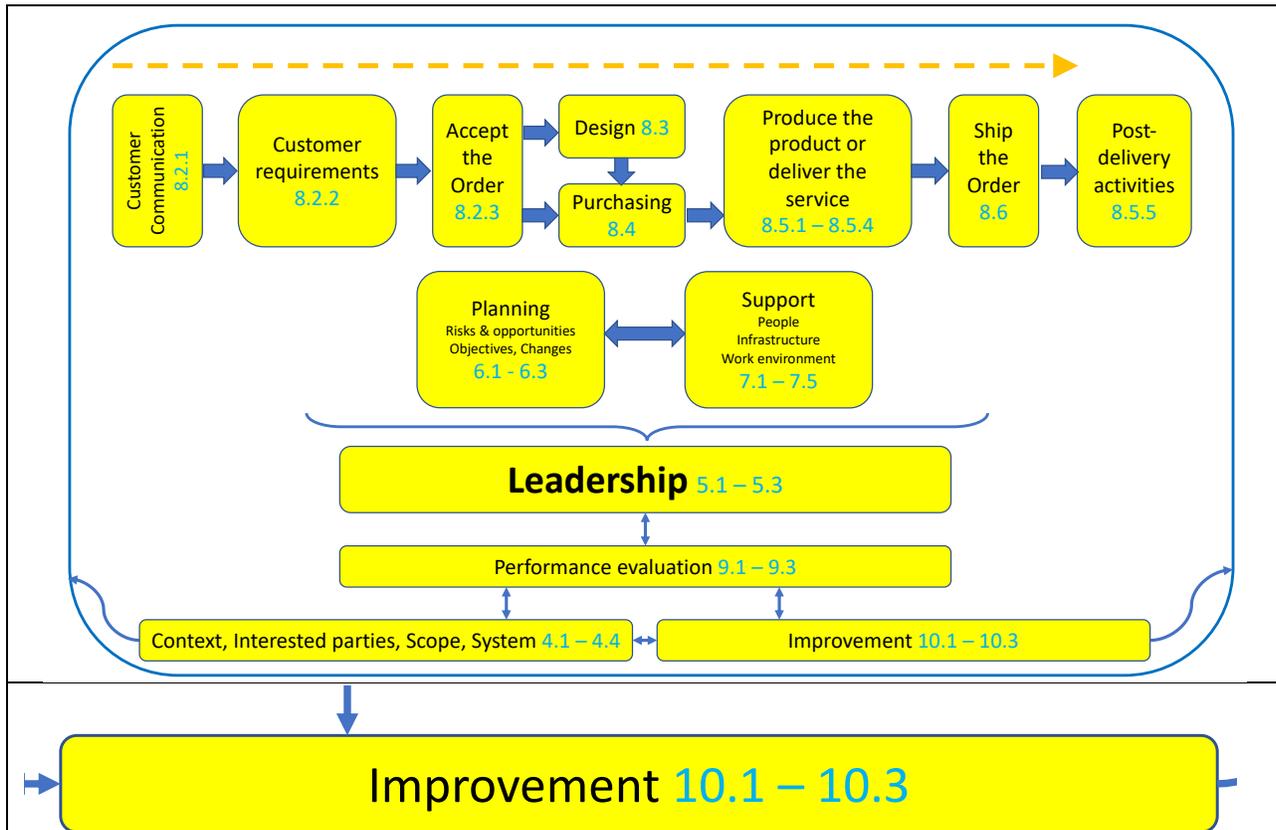
Clause 10 - Improvement

Three pillars of ISO 9001 are:

1. Customer Focus
2. The Process Approach and
3. Continual Improvement

10.1 General
The organization has to demonstrate that it has improved the effectiveness of the management system (appears 11 times in this Standard):

- Improve products or services
- Correct, prevent or reduce 'unwanted results'
- Improve the effectiveness of the management system

10.2 Non-conformances and Corrective Actions – ***"Non-conformances are nuggets of gold"***

Sources for ideas for system improvements:

Sources of Opportunities for Improvement (OFIs) or Non-conformances (NCs)

Find your nuggets of gold here:

- Customers (Internal and External)

*It costs **7 to 10** times as much money to find a new customer as it does to keep an existing customer*

- Audits (Internal and External)
- Metrics (choose any measurement methods that bring you value)
- Management Review

The 'non-conformance and corrective action' requirement has been around since 1982. Risk based thinking and analysis helps you prevent **occurrence** of problems. Corrective Action helps you prevent **recurrence** of problems*.*

Cause analysis helps you get to the root of a problem to decide on a 'corrective action' that will prevent recurrence of the 'unwanted result'. Consider using the Ishikawa Fish Bone to help you determine the reason why the problem occurred. Next, decide on a 'corrective action' and implement it. Then follow up to see if the corrective action worked.

Assess your risk analysis activities to see if you may have been able to avoid the problem. To encourage people to bring non-conformances to the table, change one question: Change the

'Who messed up?' question to "What was the weakness in our system that allowed this to happen?' People will be more willing to suggest improvements.

Corrective action = prevent recurrence.

10.3 Continual Improvement

Making the system better makes an organization more profitable, keeps employees longer, makes Stakeholders happier (Shareholders, Regulatory bodies) – benefits all around.

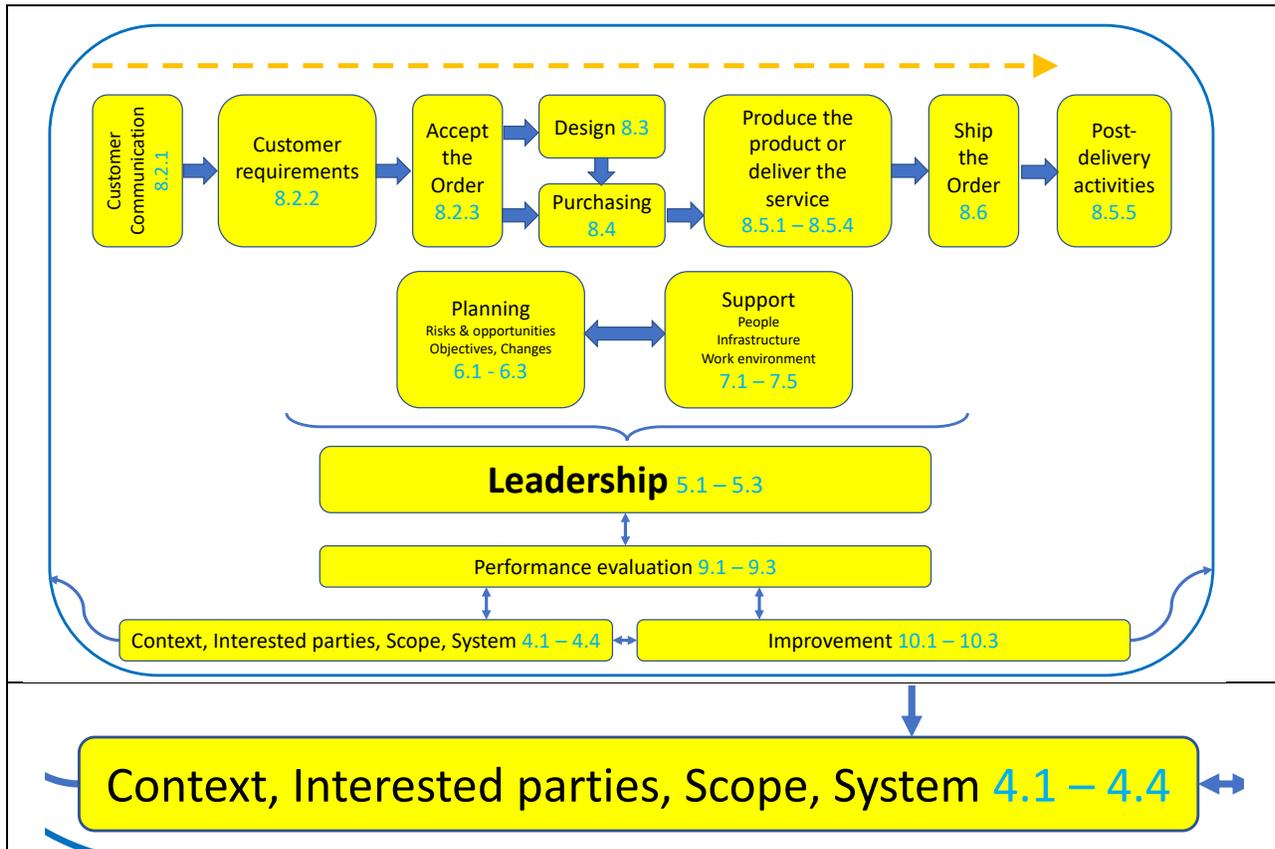**Describe what your organization does to meet these requirements:**

Clause 10 Quiz:

Open book - use your ISO 9001:2015 Standard. ***The solutions are at the end of the workbook.***

1. Opportunities to improve a management system may be found in these areas:
    a. Improving products and/or services
    b. Correcting, preventing or reducing unwanted effects
    c. Improving the effectiveness of the management system
    d. All of the above
    e. None of the above

2. When a non-conformance occurs, the organization will (**choose any that might apply**):
    a. Take action to control and correct the non-conformity
    b. Eliminate the cause of the non-conformity to prevent recurrence when necessary
    c. Review the corrective action for effectiveness
    d. Update risks and opportunities determined during planning if necessary (could we have prevented this non-conformance?)
    e. Make any necessary changes to the management system

3. Corrective Actions must be:
    a. Done as quickly as possible
    b. Appropriate to the effects of the non-conformance
    c. Kept secret from employees so they don't get the wrong impression
    d. Implemented by the same person that discovered it
    e. None of the above

4. As long as a non-conformance and the related activities are known by relevant employees, there is no need to retain documented information about it.
    a. True
    b. False

5. Continual Improvement is done to improve the _____ of the quality management system (**choose all that apply**):

    a. Suitability
    b. Profitability
    c. Safety
    d. Adequacy
    e. Effectiveness

Answers are in the ***'Solutions'*** section at the end of the workbook

Clause 4 – Context

Customer Communication 8.2.1 → **Customer requirements** 8.2.2 → **Accept the Order** 8.2.3 → **Design** 8.3 → **Purchasing** 8.4 → **Produce the product or deliver the service** 8.5.1 – 8.5.4 → **Ship the Order** 8.6 → **Post-delivery activities** 8.5.5

Planning Risks & opportunities Objectives, Changes 6.1 - 6.3 ↔ **Support** People Infrastructure Work environment 7.1 – 7.5

Leadership 5.1 – 5.3

Performance evaluation 9.1 – 9.3

Context, Interested parties, Scope, System 4.1 – 4.4 ↔ Improvement 10.1 – 10.3

Context, Interested parties, Scope, System 4.1 – 4.4

Clause 4 - Context

4.1 Understanding the Organization and its Context (see the 'Note' section below the clauses).

> You need to determine internal and external 'Issues' in order to determine your context. I prefer the word 'conditions' rather than 'issues'.

Note 1: Issues (or conditions) can be positive or negative.

Note 2: External context includes things like: Legal requirements, cultural issues, competitors, market situation, social aspects, economic environments and your whole market area.

Note 3: Internal conditions need to consider things like: culture, values. employee knowledge, skill levels, access to appropriately skilled labour.

4.2 Understanding the Needs and Expectations of Interested Parties
Interested parties are people or a group of people who can affect or be affected by your management system. You also need to understand what they want from your organization.

4.3 Scope
This is stated on your ISO certificate if you have one. If you don't, your scope is simply a description of the products and services you provide.

4.4 Quality Management System and its Processes
This section describes how your system is structured – this is the 'big picture' you've seen a few times in this presentation – 'the overview'.

4.4.1 Establish, Implement, Maintain and Improve your system
      a) Identify the processes you need to satisfy customers. Determine inputs and outputs
      b) Show the interactions of your processes (a flowchart does both a and b)
      c) Determine measurement methods
      d) Provide resources
      e) Plan responsibilities (organization chart)
      f) Address risks and opportunities
      g) Evaluate effectiveness of your system
      h) Improve the effectiveness of your system

4.4.2
Decide on how much documentation you need – at least make sure you have met all the requirements in the Standard and requirements of any regulatory bodies. It's customized to every organization and there are no specific requirements except for records (retain documented information).

Describe what your organization does to meet these requirements

Ask to have a look at the Scope, Context and Interested Parties for your organization. Become familiar with the parts of your management system that you'll be using.

Clause 4 Quiz:

Open book - use your ISO 9001:2015 Standard. *The solutions are at the end of the workbook.*

1. An organization has to do which of the following relative to its context:
    a. Determine internal issues relevant to its purpose and strategic direction
    b. Determine external issues relevant to its purpose and strategic direction
    c. Review information about its context
    d. All of the above
    e. None of the above

2. An organization has to do which of the following relative to its interested parties:
    a. Determine who they are, relevant to the quality management system
    b. Determine the requirements of the interested parties
    c. Monitor and review information about these interested parties
    d. All of the above
    e. None of the above

3. The 'Scope' of a management system typically includes or considers (**choose all that apply**):
    a. Products and services offered
    b. Internal and external issues
    c. The requirements of relevant 'interested parties'
    d. Justification for any ISO 9001 requirements that do not apply
    e. The name of the President

4. As long as everyone knows the Scope (4.3, paragraph 4)), it does ***not*** have to be maintained as documented information.
    a. True
    b. False

5. When creating the management system, and organization needs to determine the processes needed to operate the organization and (**choose all that apply**):
    a. Show the inputs required for these processes and the outputs they are expected to create
    b. Measure whether processes are creating the right results
    c. Determine the resources needed for the processes
    d. Assign responsibility to competent people for the processes
    e. Address risks and opportunities determined in the planning clause – 6.1

Answers are in the ***'Solutions'*** section at the end of the workbook

Solutions to Quizzes

Clause 8 Quiz Answers:

1. Customer communication includes: (**choose all that apply**) – Clause 8.2.1
   a. **Product and service information**
   b. **Contract and order handling (including complaints)**
   c. Special offers and financing options
   d. **Changes to orders**
   e. **Information related to customer property**

2. When deciding whether to accept an order from a customer, an organization must consider: Clause 8.2.3
   a. Customer requirements
   b. Competitors' pricing and quality
   c. Requirements not stated by the customer but necessary for the intended use
   d. Legal requirements that apply to the product or service
   e. **a, c and d**

3. The organization has to have a record (retain documented information) on the results of the review of the order and any new) customer requirements. Clause 8.2.3.2
   a. **True**
   b. False

4. Design and development controls must include (**choose all that apply**): Clause 8.3.4
   a. **The end result that the customer wants**
   b. **Information from design reviews (records of reviews)**
   c. **Verification activities**
   d. **Validation activities**
   e. Documented sign-off from the customer at each step of the design process

5. When purchasing from a supplier, an organization must consider: Clause 8.4.1, Paragraph 3
   a. The supplier's price and nothing else
   b. How the parts are packaged – purchase recyclable packaging only
   c. The amount of recycled materials in the part
   d. **The ability of the supplier to provide the process, products and services that conform to requirements**
   e. The country of origin

6. Control of production and service provision has to include (**choose all that apply**): Clause 8.5.1
   a. **Clear information about the product or service**
   b. The name of the employees who will make the product or deliver the service
   c. **Monitoring and measuring equipment**
   d. Work schedule including coffee breaks
   e. **Actions to prevent human error**

7. Property belonging to customers needs to be (**choose all that apply**): Clause 8.5.3
    a. **Identifies**
    b. **Stored in a way to keep it in usable condition**
    c. **Assessed for suitability before use**
    d. Always entered into our inventory system for inventory control
    e. Discarded if unsuitable – no mention of it to the customer

8. Organizations who do post-delivery activities need to consider: Clause 8.5.5
    a. Statutory and regulatory requirements
    b. How the product is going to be used and how long it will likely last
    c. Competitors' similar products and pricing
    d. Customer requirements and customer feedback
    e. **a, b and d**

9. Release of Products and services documentation needs to include: Clause 8.6
    a. Evidence that customer requirements have been met
    b. The names of the suppliers for all the parts in the assembly of the order
    c. The brand of packaging used and its origin
    d. The name of the person authorizing the release
    e. All of the above
    f. **a and d**

10. When controlling non-conforming products or services, the organization needs to document information about (**choose all that apply**): Clause 8.7
    a. **A description of the problem**
    b. **Actions taken related to the problem**
    c. Why the problem happened (this comes later in 'Corrective Action – clause 10.2)
    d. **Concessions obtained (e.g. money paid back to the customer or credit given)**
    e. **Who was authorized to take action related to the non-conformity**

Clauses 6 & 7 Quiz Answers:

Clause 6 Quiz answers

1. Risks are determined so that the organization (**choose all that apply**): Clause 6.1
    a. **Has more confidence that they can achieve the results that they want**
    b. Can get an ISO 9001 certificate
    c. **Make improvements to the management system**
    d. **Enhance the things that are working properly**
    e. None of the above

2. Quality Objectives must be (**choose all that apply**): Clause 6.2.1
    a. **Measurable**
    b. **Monitored**
    c. **Updated**

      d. **Communicated**
      e. **Maintained as documented Information**

3. Quality Objectives could be met with an 'action plan' that includes (**choose all that apply**): Clause 6.2.2
      a. **Actions that the plan intends to carry out**
      b. **Resources needed for the action plan**
      c. **A person or people responsible for the plan**
      d. **A timeline for completion**
      e. Unlimited budget for staff parties to celebrate milestones

4. When managing changes to the system, changes have to be planned, including: Clause 6.3
      a. Why the change is being made
      b. The possible consequences of the changes
      c. Availability of resources including people and time
      d. Changes to the organizational structure – changes in responsibilities
      e. **All of the above**

5. If risks are identified, no problems will ever occur (Common sernse!)
      a. True
      b. **False**

Clause 7 Quiz Answers

1. Resources for the operation of an organization include, but are not limited to:
      a. People Clause 7.1.2
      b. Infrastructure Clause 7.1.3
      c. Work environment Clause 7.1.4
      d. **a), b) and c)**
      e. None of the above – resources are things like lumber, water and ore

2. Provision of monitoring and measuring resources must include (**choose all that apply**): Clause 7.1.5
      a. **Suitable equipment to take appropriate measurements**
      b. The name of all employees who will take the measurements
      c. **Calibration activities to ensure that the equipment will perform properly**
      d. **Identification of the status of the measurement devices (in or out of calibration)**
      e. **Documentation of the suitability of measuring devices**

3. In order to be sure people are competent, the organization has to (**choose all that apply**): Clause 7.2
      a. **Determine what skills people need that affect the performance of the quality management system**
      b. **Make sure people have suitable experience, education and training**
      c. **Assess the effectiveness of any actions taken to improve people's competence**

    d. Keep records (retain documented information) of competence
    e. Fire anyone who isn't competent

4. In order to be sure that all persons working under an organization's control are suitably 'aware', the organization only has to give each person a copy of their Quality Policy Clause 7.3
    a. True
    b. False

5. Management System documentation may include, but is not limited to (**choose all that apply**): Clause 7.5

    a. Records of employee competence
    b. Processes the organization thinks they need to operate effectively
    c. Methods to create and update documents (policies, procedures, forms, etc.)
    d. The name of the person(s) who reviewed and approved the documents in 'c)' above
    e. A means to make sure that everyone has access to the information they need when they need it

Clause 5 Quiz Answers

1. Top Management shows leadership by (**choose all that apply**): Clause 5.1.1
    a. Making sure the Quality Policy and Quality Objectives are established
    b. Making overtime mandatory
    c. Engaging directing and supporting people to contribute to the effectiveness of the QMS
    d. Finding new customers
    e. Promoting improvement
    f. All of the above

2. Customer focus has to include (**choose all that apply**): Clause 5.1.2
    a. The lowest price
    b. Understanding and meeting customer requirements
    c. Understanding and meeting statutory and regulatory requirements
    d. Fast delivery
    e. Attention to enhancing customer satisfaction

3. The Quality Policy typically includes (**choose all that apply**): Clause 5.2
    a. A commitment to continual improvement
    b. Every product and service that the company offers
    c. A history of the organization
    d. Communication to interested parties, as appropriate
    e. Evidence that it is appropriate to the purpose of the organization

4. When organizing and delegating, responsibility is assigned to someone to (**choose all that apply**): Clause 5.3

     a. **Make sure the management system meets all of the ISO 9001 requirements**
     b. **Measure whether processes are creating the right results**
     c. **Find opportunities for improvement of the system**
     d. **Make 'customer focus' a habit throughout the organization**
     e. **Control changes to the system**

5. As long as everyone knows the Quality Policy, it does *not* have to be documented Clause 5.2
     a. True
     b. **False**

Clause 9 Quiz Answers:

1. Measurements have to be taken in these areas (**choose all that apply**): Clause 9.1.3
     a. Profitability, employee turnover and environmental performance
     b. **The degree of customer satisfaction**
     c. **The performance and effectiveness of the Quality Management System**
     d. The number of new customers per month
     e. **The performance of external providers**

2. Internal audits have to include (**choose all that apply**): Clause 9.2
     a. **A plan**
     b. **Criteria and scope for each audit**
     c. **Auditors chosen to ensure objectivity**
     d. **Documented information describing the results of the audit (like and audit report)**
     e. **Appropriate corrective actions after the audit**

3. Management Review inputs include (**choose all that apply**): Clause 9.3.2
     a. **Customer satisfaction and feedback**
     b. **Process performance, conformity of products and delivery of services**
     c. A history of the organization
     d. **Audit results**
     e. **Adequacy of resources**

4. Management Review outputs include (**choose all that apply**): Clause 9.3.3
     a. **Resource requirements**
     b. Suggested pay raises based on the system performance
     c. **Need for changes to the system**
     d. **Opportunities for improvements to the system**
     e. All of the above

5. As long as everyone has heard about the Management Review, it does *not* have to be documented Clause 9.3.3
     a. True
     b. **False**

Clause 10 Quiz Answers:

1. Opportunities to improve a management system may be found in these areas: Clause 10.1
   a. Improving products and/or services
   b. Correcting, preventing or reducing unwanted effects
   c. Improving the effectiveness of the management system
   d. All of the above
   e. None of the above

2. When a non-conformance occurs, the organization will (**choose any that may apply**): Clause 10.2.1
   a. Take action to control and correct the non-conformity
   b. Eliminate the cause of the non-conformity to prevent recurrence when necessary
   c. Review the corrective action for effectiveness
   d. Update risks and opportunities determined during planning if necessary (could we have prevented this non-conformance?)
   e. Make any necessary changes to the management system

3. Corrective Actions must be: Clause 10.2.1
   a. Done as quickly as possible
   b. Appropriate to the effects of the non-conformance
   c. Kept secret from employees so they don't get the wrong impression
   d. Implemented by the same person that discovered it
   e. None of the above

4. As long as a non-conformance and the related activities are known by relevant employees, there is no need to retain documented information about it. Clause 10.2.2
   a. True
   b. False

5. Continual Improvement is done to improve the _____ of the quality management system (**choose all that apply**): Clause 10.3

   a. Suitability
   b. Profitability
   c. Safety
   d. Adequacy
   e. Effectiveness

Clause 4 Quiz Answers:

1. An organization has to do which of the following relative to its context: Clause 4.1
    a. Determine internal issues relevant to its purpose and strategic direction
    b. Determine external issues relevant to its purpose and strategic direction
    c. Review information about its context
    d. **All of the above**
    e. None of the above

2. An organization has to do which of the following relative to its interested parties: Clause 4.2
    a. Determine who they are, relevant to the quality management system
    b. Determine the requirements of the interested parties
    c. Monitor and review information about these interested parties
    d. **All of the above**
    e. None of the above

3. The 'Scope' of a management system typically includes or considers (**choose all that apply**): Clause 4.3
    a. **Products and services offered**
    b. **Internal and external issues**
    c. **The requirements of relevant 'interested parties'**
    d. **Justification for any ISO 9001 requirements that do not apply**
    e. The name of the President

4. As long as everyone knows the Scope (4.3, paragraph 4)), it does *not* have to be maintained as documented information. Clause 4.3
    a. True
    b. **False**

5. When creating the management system, and organization needs to determine the processes needed to operate the organization and (**choose all that apply**): Clause 4.4.1
    a. **Show the inputs required for these processes and the outputs they are expected to create**
    b. **Measure whether processes are creating the right results**
    c. **Determine the resources needed for the processes**
    d. **Assign responsibility to competent people for the processes**
    e. **Address risks and opportunities determined in the planning clause – 6.1**