



ISO 9001:2008 Clauses Simply Explained

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This document has been formulated in order to explain to organizations seeking certification to the ISO 9001 : 2008 standard, the requirements of the standard in simple terms and some of the benefits of the clauses if they are applied correctly.

We hope you find this document useful and please do not hesitate to contact us with any questions.

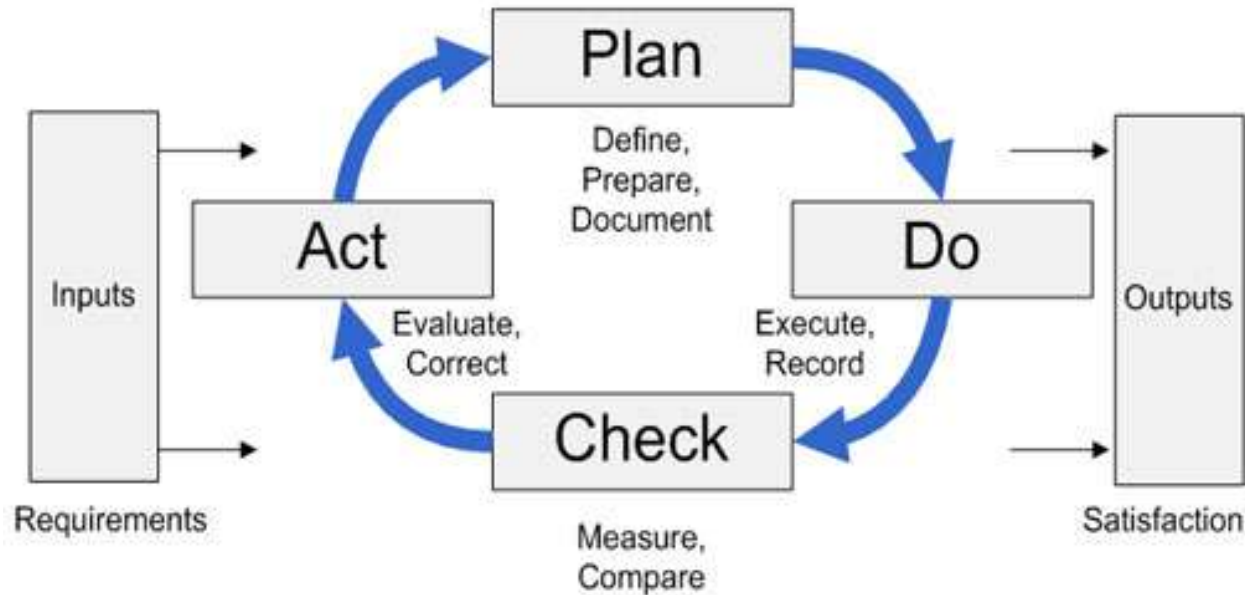


ISO 9001

Simply Explained

What it means

Lay out the processes needed by the company, and have them in sequence, making sure they are effective. Provide resources and support. Monitor and measure, and take action where necessary to improve the overall process. It must meet the ISO standard requirements.



What it means

Preparing documents is all about standardising the way you do things through policies, procedures, instructions, flow diagrams, forms etc.. Have a repeatable controlled system where records are maintained to prove compliance. In short “say what you do and do what you say” – and prove it!

How does it benefit?

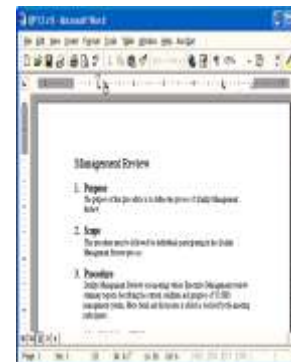
Documentation provides proof of requirements, thus providing a common source for reference. It also makes communication more reliable and removes the need for repeating and remembering verbal instructions. How does the job get done when you are not around!

Typical Records

Document master list
Procedure template
Form template



**QUALITY
MANUAL**



**QUALITY
PROCEDURES**



FORMS

What it means

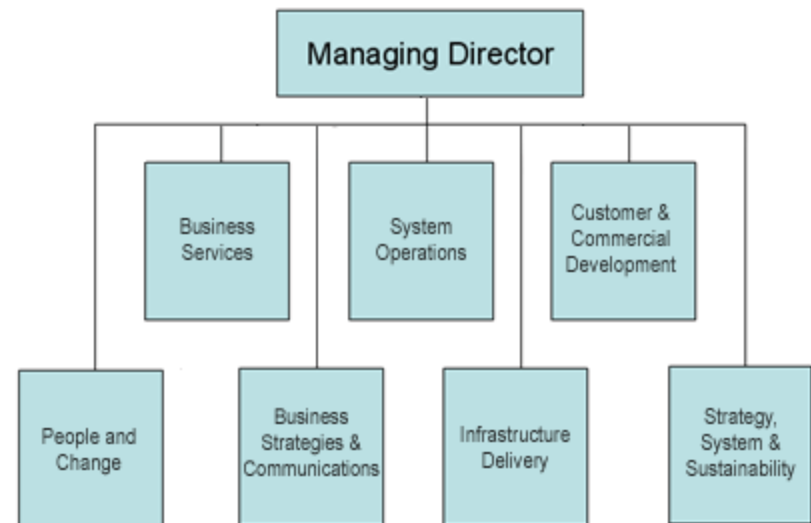
The management of the company have to be committed to putting in ISO. You have to set yourself quality objectives that can be measured. Focus on customer satisfaction, and communicate this to all employees. Define responsibilities and plan a management meeting to assess how you are doing and where you need to improve.

How does it benefit?

It shows that implementing ISO is a management initiative and will be supported right through the company. Lead by example

Typical Records

Quality Policy
Quality Objectives
Management Review
Communication Board



What it means

This part deals with the people who work for the company every day and have a quality impact on the product or service. Your employees need to have appropriate education, training and skills, and be competent to do their job. You also need a method to show that this training is effective.

How does it benefit?

Failure to train personnel may result in mistakes, & poor decisions. You cannot expect staff to do their job properly if they are not trained to do so!

Typical Records

Training induction
Training record
Training needs
Skills matrix



What it means

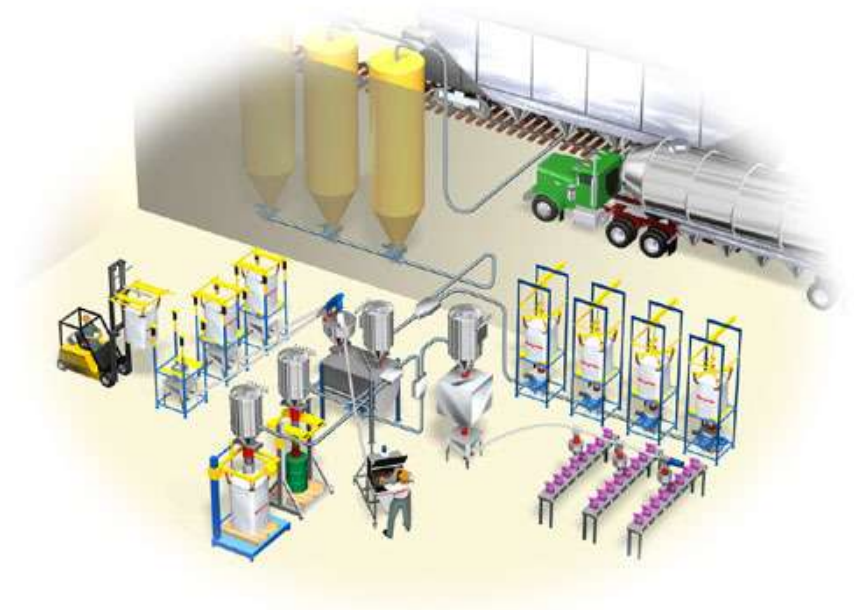
You need to identify and maintain those processes and equipment that make the product or provide the service. This includes the buildings, equipment, transport, and service.

How does it benefit?

When we take on a contract we need to provide and maintain all the necessary equipment to deliver the end result.

Typical Records

Site layout plan
Equipment list
Transport list
Process flow



What it means

This relates to the conditions under which work is performed. This includes environmental factors such as noise, temperature, humidity, lighting and weather, but also personnel work related issues so that conditions ensure the product or service is completed effectively

How does it benefit?

It's important that the environment in which we make the product or provide the service is controlled. Improvements in work environmental conditions create a positive quality culture, more satisfied workers, and thus a more satisfied customer.

Typical Records

Safety signs
Layout & Isle markings
Equipment hazards
Material handling



What it means

We need to create processes that turn the idea into a finished product or service. This needs to be planned so we ensure we can achieve our objective. We need to understand just what are the quality requirements of the product or service, and provide a method to make, measure, and prove that the finished product or service does in fact meet what we set out to do.

How does it benefit?

Sometimes called the contract review, it ensures that we actually plan and develop a process that ensure the customer will receive what they asked for.

Typical Records

Contract Review
Order detail
Quality Plan



What it means

This is much more focused on the detailed requirements that the customer actually requested. It includes all requirements specified by the customer including delivery of the product or service. It also covers the products or services intended use, statutory and regulatory requirements.

How does it benefit?

This ensures that all the detail of the product or service is well defined and recorded. Changes are controlled and people made aware. There is a clear way in which we will communicate with the customer. All these checks and balances make sure the final product or service is completed according to plan and regulation and there are clear defined lines of communication

Typical Records

Customer Information
Statutory & Regulatory
Customer drawings
Order approval



What it means

Firstly you must confirm that you actually design the products you make. If you do, then there is a step by step design process you must follow. In simple terms you are defining a method where by the customer requirements are put into suitable designs so that it is made correctly. Careful documentation is required here and maintaining all records especially change control, authorisation and communication.

How does it benefit?

You are providing all the necessary information for production, purchasing, servicing etc.. And all changes are carefully controlled and documents suitably identified.

Typical Records

Drawings
Acceptance Criteria
Industry Standards
Statutory requirements



What it means

You have to ensure that the material you purchase, is in fact suitable for it's intended purpose. This includes assessing your suppliers. You need to make sure that your purchase orders clearly specify what you need, and also you have a method to confirm it meets this requirement when received

How does it benefit?

Remember you are a customer too, and in order for you to meet your customer requirements you have to ensure that the material purchased is what was intended, and have a method to monitor and control this. The quality of what you receive will directly affect your customers

Typical Records

Purchase orders
 Supplier Qualification
 Receiving checklist
 Approved supplier list

QTY	MODEL NO.	DESCRIPTION	UNIT PRICE	TOTAL AMOUNT
1	SH1500	MAT BOISTY STORAGE SYSTEM FOR 15 x 40' MATS (see product description)	\$8,300.00	\$8,300.00
1	N/A	Mat Hais Voltage?? 200V, 230V or 480V	N/C	N/C
6	CL-1	CL-1 UNIT CLAMP	\$48.75	\$292.50
Special Instructions:			TOTAL	59312.50

FROM: Your Company
 1122 Cherry Lane
 San Diego, CA 92116

VENDOR: NGE INC
 PO BOX 376 INDUSTRIAL PARK
 ROLAND, LA 70734

SHIP TO: CENTRAL HIGH SCHOOL
 120 E. MAIN STREET
 FORT MILL, SC 29715-1848

SHIP VIA: AHP Freight FOB POINT: Roland, Iowa EST. SHIP DATE: March 2009 SUBMITTED BY: Sue Jones

APPROVED SIGNATURE

What it means

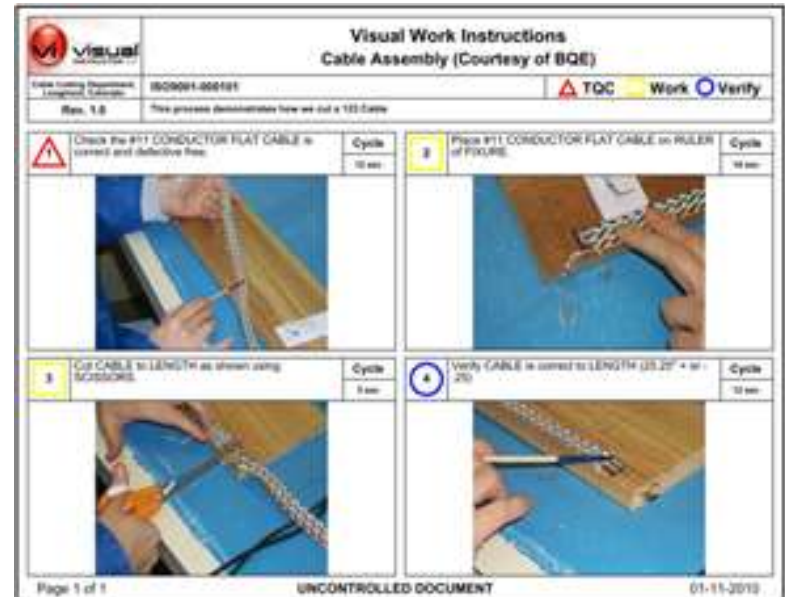
When the employees are making or servicing the product they must have adequate information, process equipment and measuring equipment in order to turn materials into a finished product. It basically means that production or service is controlled and follows a standard process.

How does it benefit?

If you have all the information and process controls needed to make a product or provide a service, then you will get a repeatable process that is consistent, meet requirements, and satisfy the customer every time.

Typical Records

- Process Flow Diagrams
- Work Instructions
- Job Cards
- Workmanship Standards



What it means

Depending upon your product or service this may or may not be required. It's only needed where a product characteristic cannot be verified before shipment and a problem may only become apparent after the product is in use. Therefore you need a method to confirm it will meet its intended purpose.

How does it benefit?

An example would be where welding is done and there is a method used to qualify the people and equipment. Some processes are dependent upon personnel, equipment and facilities used and cannot be verified by examination. You have got to ensure such characteristics do not fail in use.

Typical Records

- Competence Training
- External test records
- Equipment validation
- Test piece records



What it means

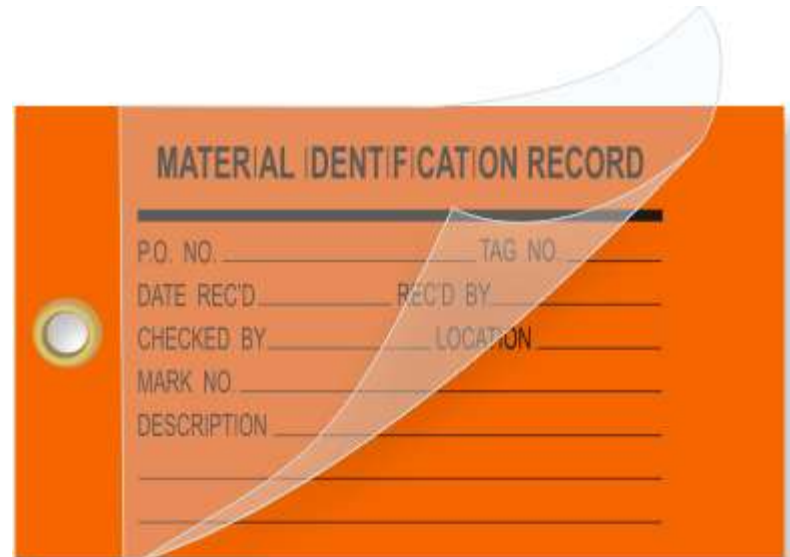
You need to know the identity of a product. This avoids using the wrong material, or mix-up's in production or service. It doesn't mean that every piece of material has to have ID, but a means suitable to tell what the status is. There are various ways to control this, including "by location", but it must be clear. Traceability is a step further where you have a unique ID that can be traced back to source.

How does it benefit?

Material mix-up's are very costly in terms of dissatisfied customers, but also waste in production. This waste includes scrap, rework, time searching, stock-outs etc.

Typical Records

Area Locations
ID Tags
Barcodes
Unique product ID



MATERIAL IDENTIFICATION RECORD

P.O. NO. _____	TAG NO. _____
DATE REC'D _____	REC'D BY _____
CHECKED BY _____	LOCATION _____
MARK NO. _____	
DESCRIPTION _____	

7.5.4 CUSTOMER PROPERTY

What it means

This could be material, equipment or intellectual property supplied by the customer to be used in your process. You need to exercise care, and ensure its identified and protected throughout the process. If you lose, damage or find it's unsuitable then you need to inform the customer and keep records of this.

How does it benefit?

There are occasions where you have to use your customers property in supplying a product or service. This clause just ensures you look after it, and have a method to report any damage etc to the customer. It all helps in keeping a very positive customer relationship.

Typical Records

Equipment list
Material ID tags
Damage reports



What it means

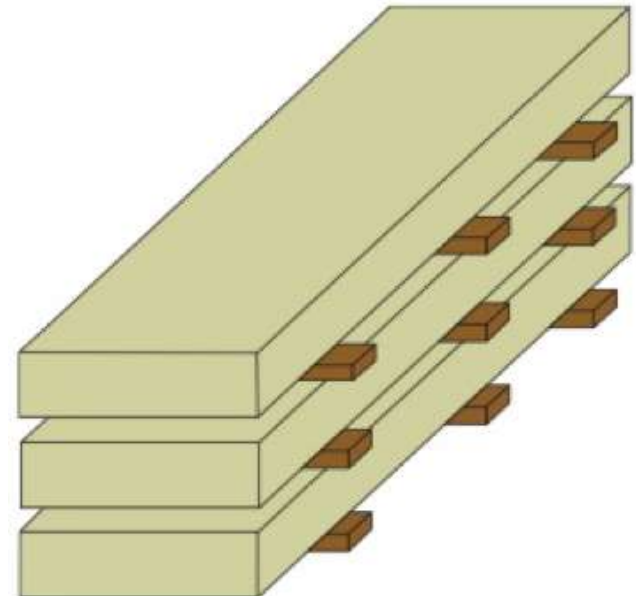
How you preserve product will depend upon the type of product you make, or the service you provide. You are ensuring that you ID, handle, pack, store and protect product from raw material through to delivery in a way suitable to prevent damage.

How does it benefit?

You can spend a lot of time and money making and checking products only to fail at maintaining the quality through poor handling, storage and packaging. It's very important that there are systematic methods to preserve product right through the entire process until it reaches the customer.

Typical Records

Adequate storage location
Isle markings
Handling procedures
Acceptance procedures



What it means

Sometimes better known as “calibration” this clause ensures that the measuring equipment you use to measure the product or service is adequate to meet the customer requirements and is safeguarded from unintended use. Also the equipment is checked at frequent intervals to confirm its in specification. If a problem is found then there must be a way to review product already measured using the device.

How does it benefit?

It's important to point out that not all inspection equipment requires calibration. (ex. Ruler) However the key point here is that the equipment is adequate to measure the characteristic, and has been assessed for frequency of calibration and measuring capability.

Typical Records

Inspection equipment list
Calibration stickers
Equipment accuracy
Corrective action report

CALIBRATION	
BY _____	DATE _____
DUE _____	



What it means

This is all about how the customer perceives your product and service. Just because a customer hasn't complained about your product or service doesn't mean they are satisfied. Come up with a way to monitor the customer and use this data to improve the relationship.

How does it benefit?

By ensuring you keep the customer satisfied you will get repetitive business and also new customers. You need to take advantage of many ways of gathering customer data. This information should feed into the corrective action procedure and analysis of data to be also used in management reviews.

Typical Records

Customer satisfaction survey
Customer complaints
Analysis of lost business
Warranty claims
Phone in log



What it means

Your company must have a method to confirm that you comply with the standard. You need to have a planned audit programme covering all areas of the standard. These audits will signal where action is needed, and address problems with the system. Auditors must be trained and independent of the area they are auditing.

How does it benefit?

Without checks on the system, standards will deteriorate. Therefore if there is no warning that something is wrong, product or service will not be adequate and the customer will suffer.

Typical Records

Annual audit schedule
Audit findings record
Training records
Corrective action report



What it means

You need to monitor and measure the processes that make up the quality management system.

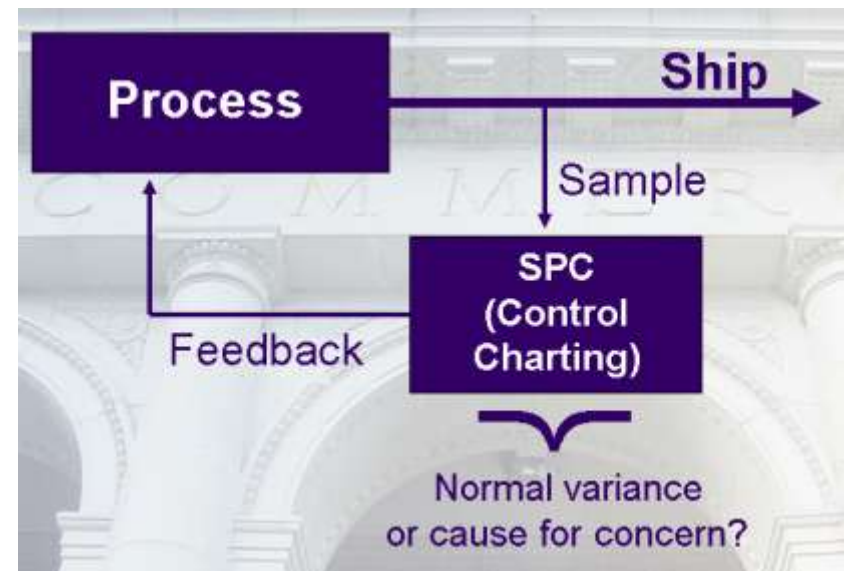
Consideration should be given to processes that have the highest impact on product or service quality, and when results are not adequate, take corrective action.

How does it benefit?

Processes vary depending upon the product or service you supply, but it's important that these processes are well controlled and the method you choose to monitor is adequate to ensure customer satisfaction.

Typical Records

Check lists
Process input / output flow
Control charts
Feedback flag system



What it means

You must have set criteria to measure the key characteristics of the product or service. This ensures that the requirements have been met from the initial plan. This should be done at appropriate stages. You need to provide evidence of these checks, and record the final check and person who does final release.

How does it benefit?

Before you ship any product or complete a service, you have to be satisfied that it meets its intended purpose and all the checks and balances have been done.

Typical Records

Product acceptance criteria
Drawing inspection
Final release checklist
Sample audit

VISUAL INSPECTION



Appliance ID:

Date:

Next Due:

Engineer:

PASS ✓

What it means

In simple terms, if there is something wrong with a product, it must not be shipped to a customer.

Therefore there needs to be a method to identify this material, make sure it cannot be used by mistake and ultimately decide what you are going to do with it. It may be scrapped, reworked, or used-as-is, but this must be approved by an authorised person/group .

How does it benefit?

By making sure that nonconforming product is controlled from mixing with good product, you ensure that the customer does not receive unacceptable, or unsafe product and hence irate customers. Failure to control can be very expensive

Typical Records

- Non conforming tags
- Segregated hold areas
- Non conforming material report
- Disposition (what we do with it)
- Corrective action report



What it means

The collection of good quality data that can be used to demonstrate how well you are doing is key to assess where you need to improve. You should be collecting and analysing information relating to customer satisfaction, product quality, process trends, suppliers and opportunities for improvement.

How does it benefit?

By collecting and analysing data you know where the greatest opportunities lie for improvement. The emphasis should always be on the customer, and how you can improve upon what you do now.

Typical Records

Customer surveys
Non-conformance reports
Supplier evaluation
Internal audits
Trends



What it means

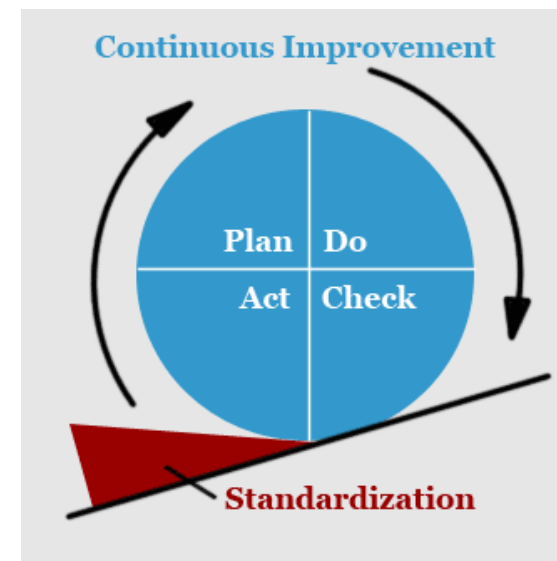
One of the most important elements of this quality system is the area of continuous improvement, and the use of corrective and preventative action reports. These are used both to correct a known problem, but also to prevent their occurrence. Corrective and preventative action reports follow a very structured format identifying the problem and implementing permanent measures to improve the system

How does it benefit?

The effectiveness of your quality management system depends on how quick you are able to react to problems that come up, and also methods to predict problems. Customers understand that a problem can arise, but it's how you address them and prevent them from occurring again is the key

Typical Records

- Quality objectives
- Audit results
- Customer complaints
- Corrective action reports
- Preventative action reports



If you have decided to get certified to ISO 9001

Give us a call

We will assess what you will need (FREE)

We will audit your process (FREE)

Provide options (FREE)

Recommend the best method (FREE)

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