ISO 9001 - STAGE 2 FOR LARGER ORGANISATIONS

Judith Hargreaves
LLB Hons

12th July 2021

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NQA specialises in certification in **high technology** and engineering sectors.

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RISK MANAGEMENT


MEDICAL DEVICES

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KEY INFO

- 45 minute webinar
- Questions in the chat box
- Q&A at the end
- Recording of webinar circulated shortly

YOUR PRESENTER

Judith Hargreaves

ISO 9001, ISO 14001, ISO 45001, PAS43, SSIP, NHSS 17

NQA Regional Assessor

Judith is a lead assessor for ISO 9001, 14001, 45001, PAS43 and NHSS schemes, and leads assessments for some of NQA's largest clients. It is the responsibility of the assessor to ensure compliance to the Standards are evidenced and work with clients to ensure they are getting the most value out of the Standard they are certified to. Judith's industry experience and personal achievements across a variety of sectors sets her in a perfect position to support NQA clients with added value services such as webinars, blogs and videos.

OBJECTIVES OF TODAY'S WEBINAR

Practical implementation…

- Differences between smaller and larger organisations from an ISO Standard point of view
- How to prepare the organisation
- Value the audit can bring
- Communications and who should be involved

WHY ARE LARGER ORGANISATIONS DIFFERENT?

- ISO 9001 can be seen as a corporate tool and not reach everyone
- The larger the organisation the more ‘pockets’ appear
- People who have worked in other organisations prior to this may have experience of old ISO 9001 Standards
- It’s assumed more resource makes it easier to create, run and achieve an ISO 9001 system

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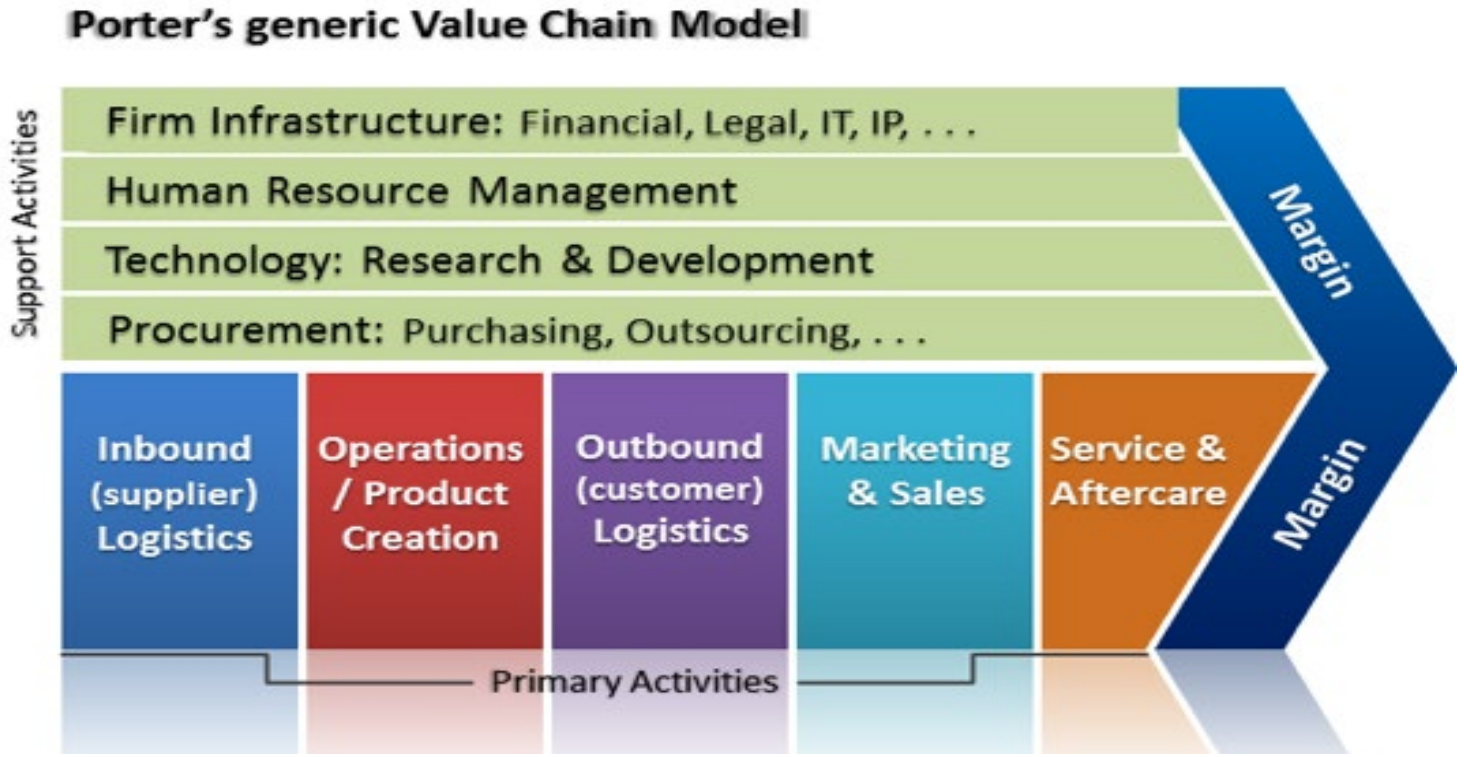
GOOD NEWS!

HOW TO PREPARE THE ORGANISATION

- Scope - maintain support to operation of processes, provide confidence processes work
- Interested Parties – who is affected by the company, and how can others (e.g. regulators or competition) affect us?
- Internal and external issues – we all have these regardless of our role
- What processes do we follow e.g. software led system, client led, change requests, work instructions

ROLES AND RESPONSIBILITIES



LEADERSHIP

- The top management/leadership is often more complex in a larger organisation, more levels and potentially distanced approach
- Managers and supervisors will often disseminate information relevant to the KPI's to each section of the business
- As it is not H&S, (although preferable), we don't always need to speak to the complete top management if it has been delegated and suitably accounted for
- We do need to see the input for the policy and objectives to ensure that top, top management is not removed form the system

PLANNING

The requirement of planning is ensure the system can achieve its objectives, plan actions to address risks and opportunities, and achieve improvement:

- The implementation of this is everyone's responsibility and therefore the communication of the planned objectives is a critical aspect of the Standard as well as policy
- It is the case that auditors expect all staff to know their role in the system and their department objectives, we will dig deeper with top management as to how and why these are set
- The policy should be understood and accessible by all in the company, however we would not expect anyone to be able to recite it! Just be aware and know your part

PLANNING OF CHANGES

This is a hot spot in larger organisations in terms of audit findings:

The processes are set and integrated often taking into account many factors such as;

- Will one process affect another?
- Resources
- Statutory and regulatory requirements
- Customer requirement

Process users often find a different or better way to conduct their part, if the change is not planned and IN the system this can become a non-conformance.

SUPPORT

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system:

- Internal resources
- What do we need from external providers?
- People who can follow and bring improvement to the system
- Work environment eg internet, buildings, transport, social, physical and psychological factors
- Monitoring of resources – maintaining fitness for purpose
- Traceability – can be documentation or physical such as calibration

SUPPORT

- Organisational knowledge
- Competence – may be time served, certificates, it is determined by the company unless there is a statutory requirement
- Awareness – As mentioned: policy, objectives, your contribution and implication of not conforming
- Communication – The top management will determine what, when and how information is communicated and to who; we will get this from them and verify whether you have received this.

DOCUMENTED INFORMATION

Main findings:

- It is not controlled
- People cannot find what is needed
- Not always accessible e.g. internet issues
- Out of date versions
- Saved incorrectly
- Not available as per a procedure, or procedure not updated

OPERATIONAL PLANNING

- Determine requirements for products and services – can you meet what the customer wants?
- Customer communication – enquiries, contracts, changes, feedback, customer property, contingency plans
- Can we meet the claim for products and services? (Statutory and Regulatory)
- Document if there is a change

DESIGN AND DEVELOPMENT PLANNING

- Nature and duration
- Process stages
- Verification and validation
- Responsibilities of those involved
- Resources
- Control of interfaces between persons
- Customer input
- Levels of control

Documents to evidence this!

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DESIGN INPUTS AND CONTROLS

- Functional and performance inputs
- Information from previous designs which may provide value
- Statutory and Regulatory
- Standards and codes of practice
- Potential failure and consequence
- Results to be achieved
- Reviews to ensure designs and developments can meet requirements
- Verification and validation of application
- Problem solving
- Outputs will include that requirement is met, monitoring and measuring to prove acceptable criteria, and specifically they are fit for purpose and safe
- Changes will look at: reviews, authorisation and actions to prevent adverse effect

EXTERNALLY PROVIDED PROCESSES

Control of suppliers may include a PQQ, a customer requirement, a company judgement. It is the responsibility of the company to ensure the requirements can be met, and communicate:

- Requirements to be met
- Approval of product and service, methods, release of product
- Competence of the provider
- Verification or validation of activities

You may have auditors, sample quality checks, customer aftercare to ensure these are met post delivery.

As ever changes throughout should be documented.

CONTROL OF NON-CONFORMING OUTPUTS

The organisation needs to deal with products that do not conform. This may include:

- Segregation or containment
- Informing the customer
- Authorisation for acceptance or concession
- Correction

These steps must be documented.

More and more we see only audit findings as NC's, if you deal with things at the time as quick fix you won't be able to easily identify trends and know where improvements can be made.

PERFORMANCE EVALUATION

The quality system requires regular evaluation to monitor its effectiveness:

- What?
- Methods
- When?
- Results

What do we do with the results?

Customer Satisfaction: Determine the methods to capture perception.

ANALYSIS

We are required to look at the data we have gathered within the previous steps, and this will generally be done at a management level:

- Conformity of products and services
- Customer satisfaction
- Performance of the system
- Has planning been implemented effectively?
- Actions taken to address risk and opportunity

INTERNAL AUDIT

- A full process audit must be planned at intervals to assess whether the system conforms to its own requirements and also the Standard
- The plan shall include frequency, methods and responsibilities taking into account the importance of processes
- Audit criteria should be defined with a scope for each audit
- Auditors should be objective and impartial to the audit process
- Report results to relevant management
- Take appropriate corrective action without undue delay
- Retain documents

MANAGEMENT REVIEW

Must be planned and include all inputs as determined by the Standard:

a) The status of actions from previous management reviews;
b) Changes in external and internal issues that are relevant to the quality management system;
c) Information on the performance and effectiveness of the quality management system, including trends in:
   1) customer satisfaction and feedback from relevant interested parties;
   2) the extent to which quality objectives have been met;
   3) process performance and conformity of products and services;
   4) nonconformities and corrective actions;
   5) monitoring and measurement results;
   6) audit results;
   7) the performance of external providers;
d) The adequacy of resources;
e) The effectiveness of actions taken to address risks and opportunities (see 6.1);
f) Opportunities for improvement.

IMPROVEMENT AND CONTINUAL IMPROVEMENT

A large incentive of having the Standards is to reduce risk but to also improve:

- Improve product or service
- Correct or prevent undesired effects
- Improve performance of the system

NONCONFORMITY AND CORRECTIVE ACTION

When any type of nonconformity occurs we must:

- React
- Take action to control and correct
- Deal with consequences

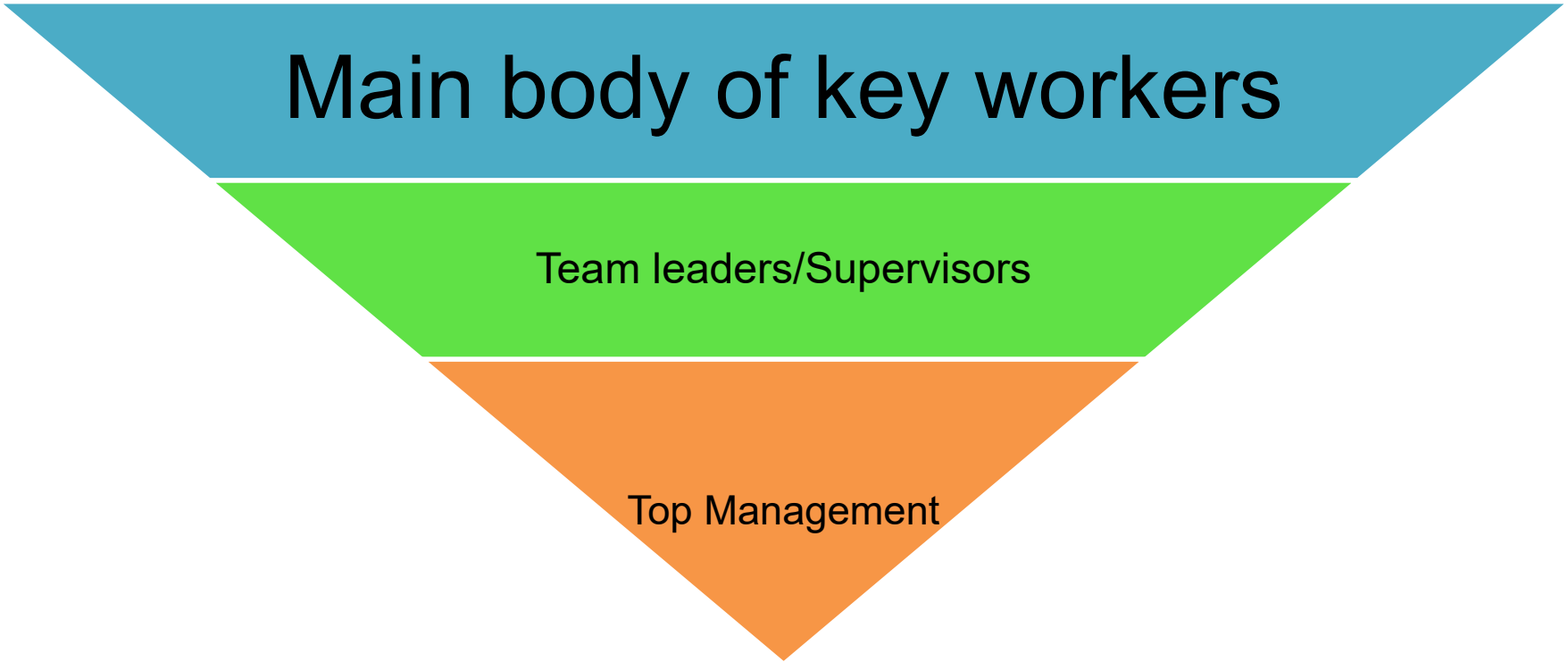
NONCONFORMITY AND CORRECTIVE ACTION

Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1. Reviewing and analysing the nonconformity;
2. Determining the causes of the nonconformity;
3. Determining if similar nonconformities exist, or could potentially occur;
4. Implement any action needed;
5. Review the effectiveness of any corrective action taken;
6. Update risks and opportunities determined during planning, if necessary;
7. Make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

TAKEAWAY


Main body of key workers
Team leaders/Supervisors
Top Management

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- Annex SL Comparison Tool download
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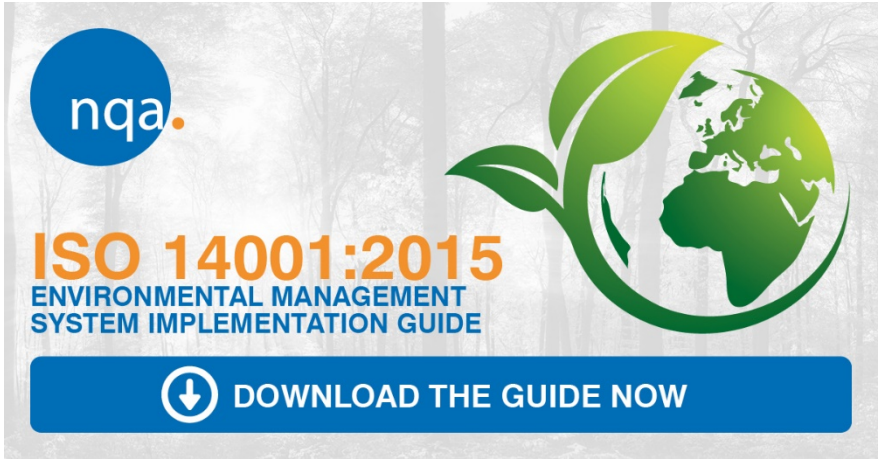

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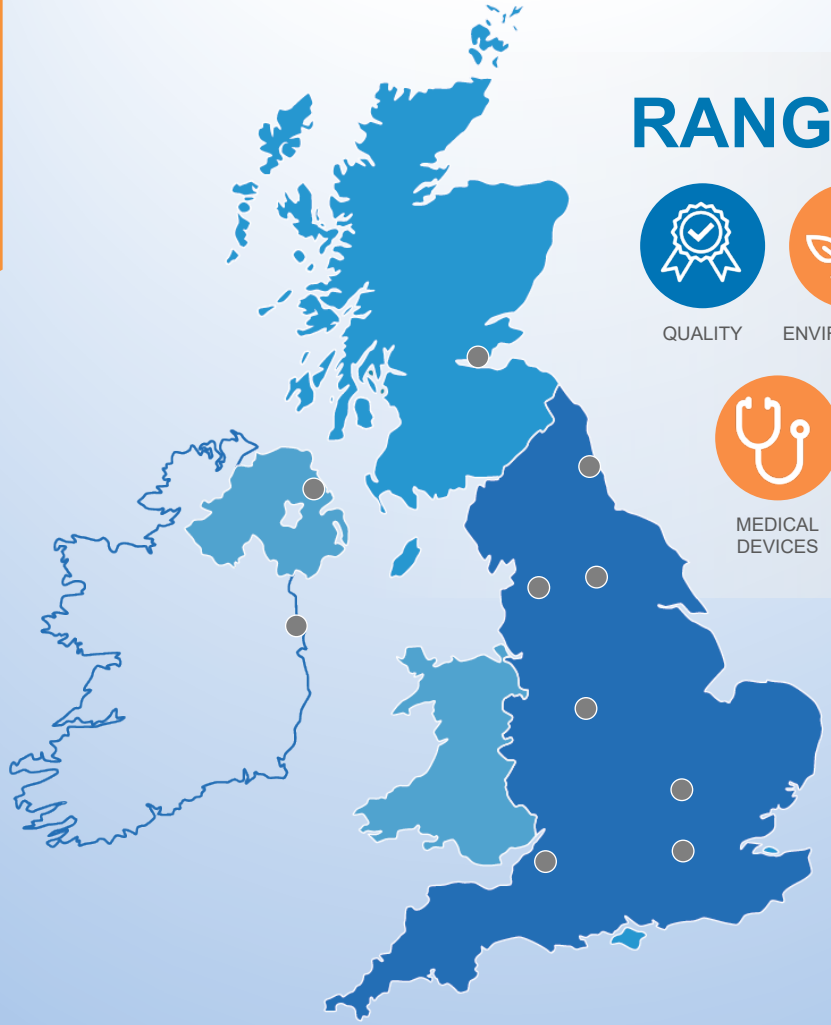

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Q&A

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