# WAYS TO DOCUMENT EVIDENCE ISO 9001:2015

Michael Venner

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# OUR PURPOSE

IS TO HELP CUSTOMERS DELIVER PRODUCTS THE WORLD CAN **TRUST**

NQA is a **world leading certification body** with global operations.

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

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**AMERICA'S NO.1**
Certification body in **Aerospace** sector

**TOP 3 IN THE UK**
ISO 9001, ISO 14001, ISO 45001, ISO 27001

**CHINA'S NO.1**
Certification body in **Automotive** sector

**GLOBAL NO.1**
Certification body in **telecommunications** and **Automotive** sector

**UK'S NO.2**
Certification body in **Aerospace** sector

**GLOBAL NO.3**
Certification body in **Aerospace** sector

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**50,000**
**CERTIFICATES**
GLOBALLY

**100%**
**ALL INCLUSIVE**
FEES

**1000+**
**EMPLOYEES**
WORLDWIDE

**10**
**YEARS**
AVERAGE
**CUSTOMER**
**PARTNERSHIP**

OVER **90**
OPERATING
**COUNTRIES**

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# CERTIFICATION AND TRAINING SERVICES

## We specialize in management systems certification for:

QUALITY

AEROSPACE (QUALITY)

AUTOMOTIVE (QUALITY)

ENVIRONMENT

ENERGY

HEALTH AND SAFETY

INFORMATION RESILIENCE

FOOD SAFETY

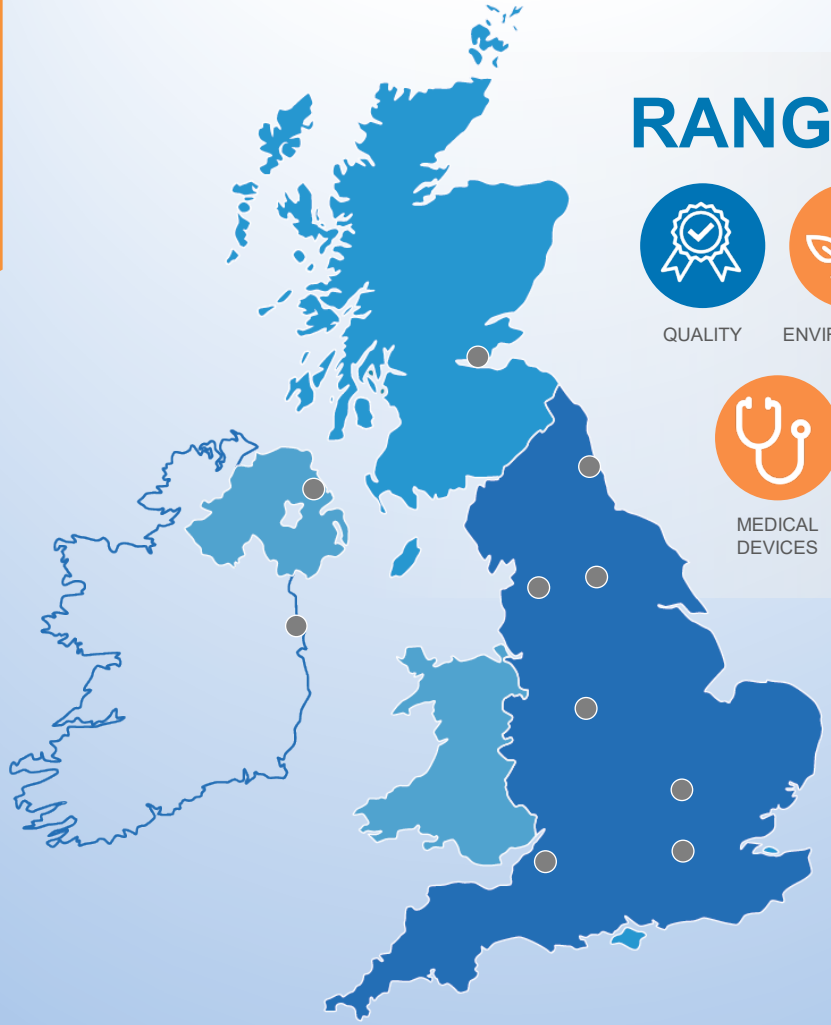
RISK MANAGEMENT

MEDICAL DEVICES

# NATIONWIDE TRAINING SERVICES

ACCREDITED COURSES

- Virtual Learning
- e-Learning / Live Webinars
- In-house Training
- Public Training Nationwide Locations



## RANGE OF COURSES

- QUALITY
- ENVIRONMENT
- ENERGY
- HEALTH AND SAFETY
- INFORMATION SECURITY
- MEDICAL DEVICES
- BUSINESS CONTINUITY
- AEROSPACE
- INTEGRATED MANAGEMENT

- **e-Learning** Introduction
- **1 day** Introduction Courses
- **2 day** Implementation Courses
- **2 day** Internal Auditor – NQA or IRCA
- **5 day** Lead Auditor – NQA or IRCA
- **Advanced** Training

CQI | IRCA
APPROVED TRAINING PARTNER

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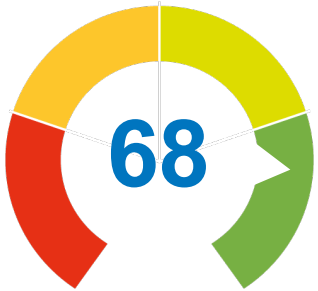
# OUR PROMISE TO YOU




**NET PROMOTER SCORE**

## NQA'S EXPERIENCE PROMISE

- We promise to update you on industry changes
- We promise our experience will add value to your audit schedule
- We promise to ensure your certification remains flexible to your business
- We will ensure all fees are all inclusive
- We will ensure our auditors are technically competent for your industry
- We will deliver excellent customer service
- We will provide added value through our audits and reports
- We will provide access to a customer portal

"NQA's approach is practical and proactive. Our auditor understands our business."

**GLENMORANGIE**

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## KEY INFO

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

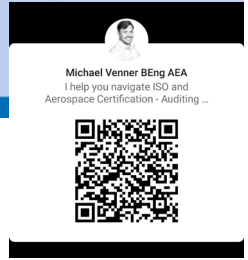
# YOUR PRESENTER

## Michael Venner

AS9100, AS9120, AS6081, ISO 9001, ISO 14001, ISO 45001, NEBOSH

**NQA Aerospace and Automotive Director**

Mike has over 17 years' experience in management system development and deployment. Specialising in the AS9100 and AS9120 Aerospace Management System standards. An industry expert, widely trusted and respected amongst peers for managing an efficient and effective Aerospace and Automotive business unit within NQA.



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# WHAT WILL YOU LEARN?

- How to create a lean ISO 9001:2015 system without unnecessary paperwork
- Where does the Standard require documented information?
- “I want to help my work force be more efficient by reducing documented information – how do I evidence the requirements are still met to an auditor?”
- Where to start when considering reducing and updating your system; important planning.

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# What the Standard Requires

## ISO 9001

**4.4.2 To the *extent necessary*, the organisation shall:**

**a) Maintain documented information to support the operation of its processes;**

**b) Retain documented information to have confidence that the processes are being carried out as planned**

**7.5.1 Documented Information**

**The organization's quality management system shall include:**
**a) documented information required by this International Standard;**

**b) documented information determined by the organization as being *necessary for the effectiveness* of the quality management system.**

**NOTE The extent of documented information for a quality management system can differ from one organization to another**

## ISO 9000

3.8.6 Documented Information

Information (meaningful data) required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in **any format** and media and from any source.

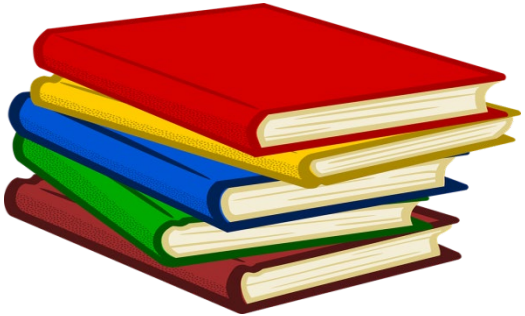
Note 2 to entry: Documented information can refer to:
— the management system, including related processes;

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

# WHAT DOES YOUR QUALITY MANAGEMENT SYSTEM LOOK LIKE?

**It is likely (from what we see daily) that you have:**



- A quality manual – DUSTED OFF ONCE A YEAR
- A written Policy within the manual and on a noticeboard – IS IT RELEVENT?
- Folders of written procedures/flowcharts on walls – WHO READS THEM?
- Management review minutes – ARE THESE NEEDED?
- A non-conformance register – HOW IS IT MANAGED?
- Internal Audits – ARE THEY EFFECTIVE?

# The Quality Manual

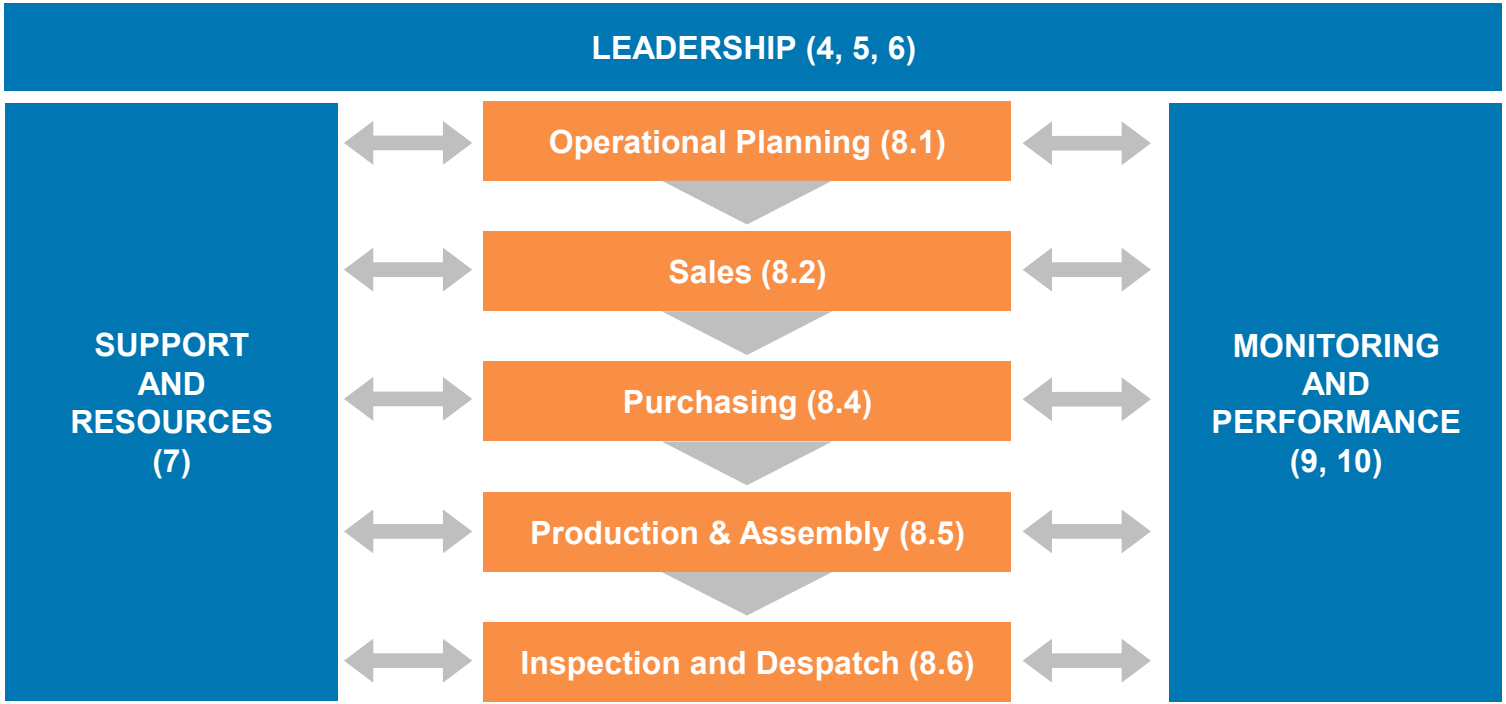
**What we see daily:**

**A manual which doesn't provide much information such as an almost direct copy and paste of the Standard such as:**

We have established, implemented, maintain and continually improve a quality management system, including the processes Needed and their interactions, in accordance with the requirements of this International Standard.

We have determined the processes needed for the quality management system and their application throughout the organization, and have:
a) determined the inputs required and the outputs expected from these processes;
b) determined the sequence and interaction of these processes;
c) determined and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d) determined the resources needed for these processes and ensure their availability;
e) assigned the responsibilities and authorities for these processes;
f) addressed the risks and opportunities
g) evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results.

# What Makes Life Easier



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# DOCUMENTED INFORMATION-64 Places

| SECTION | REQUIREMENT |
|---|---|
| 4. CONTEXT OF THE ORGANISATION | The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system |
| 5. LEADERSHIP | Policy |
| 6. PLANNING | Objectives |
| 7. SUPPORT | The organization shall retain ***appropriate documented information*** as evidence of fitness for purpose of the monitoring and measurement resources.<br><br>The basis used for calibration or verification shall be retained as documented information<br><br>retain appropriate documented information as evidence of competence. |

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# WHAT THE STANDARD REQUIRES PART 2

| SECTION | REQUIREMENT |
|---|---|
| 8.1 Operation planning and control | 1) to have confidence that the processes have been carried out as planned;<br>2) to demonstrate the conformity of products and services to their requirements. |
| 8.2 Requirements for products and services | 1) on the results of the review<br>2) any new requirements for products and services<br><br>The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed. |
| 8.3 Design and development: planning, inputs, controls, outputs and changes | 1) 9 requirements to consider when planning, ensure documented information met such as: resources, verification and validation, customer involvement, level of control, design reviews, responsibilities<br>2) Document design inputs<br>3) Document controls on verification and validation<br>4) Document outputs<br>5) Document changes; results of reviews of changes |

# WHAT THE STANDARD REQUIRES PART 2

| | |
|---|---|
| 8.4 control of externally provided processes and resources | Evaluation, selection, monitoring of performance and any subsequent actions |
| 8.5 Production and service provision | the availability of documented information that defines:<br>1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;<br>2) the results to be achieved;<br>2) retain the documented information necessary to enable traceability<br>3) Property belonging to customers or external source lost, damaged or otherwise found to be unsuitable for use,-actions taken and comms<br>4) the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review. |
| 8.6 Release of products and services | 1) evidence of conformity with the acceptance criteria;<br>2) traceability to the person(s) authorizing the release. |
| 8.7 Control of non-conforming outputs | 1)describes the nonconformity;<br>2) describes the actions taken;<br>3) describes any concessions obtained;<br>4) identifies the authority deciding the action in respect of the nonconformity. |

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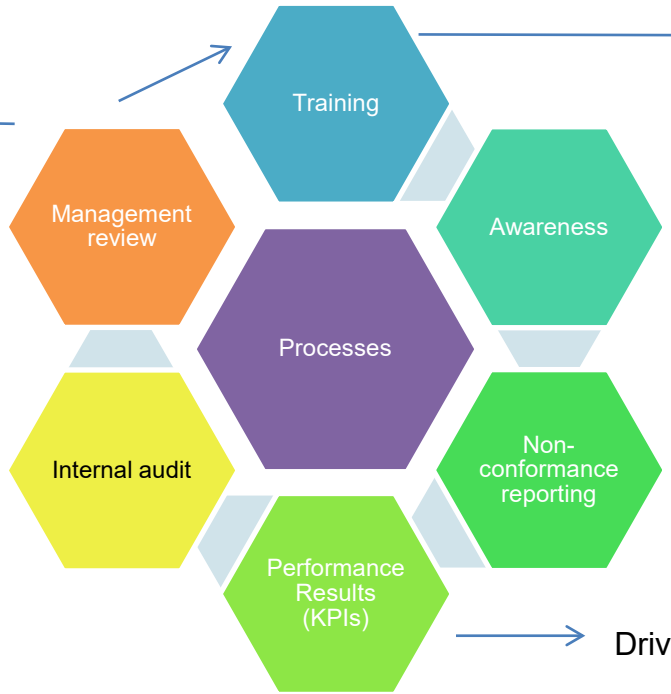
# WHAT THE STANDARD REQUIRES PART 2

| SECTION | REQUIREMENT |
|---|---|
| 9. Performance Evaluation | The organization shall evaluate the performance and the effectiveness of the quality management system.<br><br>The organization shall retain appropriate documented information as evidence of the results. |
| 9.2 Internal Audit | retain documented information as evidence of the implementation of the audit programme and the audit results. (Audit programme, audit records, NCRs and actions) |
| 9.3 Management Review | retain documented information as evidence of the results of management reviews (only really asking for actions from reviews) |
| 10.2 Non-conformity and corrective action | 1) the nature of the nonconformities and any subsequent actions taken;<br>2) the results of any corrective action. |

# "I WANT TO HELP MY WORK FORCE BE MORE EFFICIENT BY REDUCING DOCUMENTED INFORMATION – HOW DO I EVIDENCE REQUIREMENTS TO MY AUDITOR?"

Management shall review, not management shall have a meeting once a year and generate minutes. Truly think about your review points and who is involved.




Starts at a thorough induction and refreshers which we can evidence

Discussion, demonstration

By showing issues, or points for learning you are evidencing utilisation of the system and effectiveness of the processes.

Drives Improvements

An opportunity to assess the system and see what can be removed and or refined. You may find too many processes that do not talk to each other, inefficient use of technology

# ADVANCED TRAINING COURSES

- Leadership within ISO
- Effective management of change
- Managing your supply chain relationships
- Effective evaluation of compliance
- How to identify risks & opportunities
- Participation & consultation of workers
- Demonstrating customer satisfaction
- Managing information security remotely
- Generating an acceptable use policy
- Operational resilience planning
- Effective root cause analysis

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# Q&A

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# THANK YOU

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