



# **ISO 9001:2015 BACK TO BASICS – INTERNAL AUDITING**

---

**Martin Graham**

---

**Principal Assessor - QMS**

---

# 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.



## AMERICA'S NO.1

Certification body in  
**Aerospace** sector

## GLOBAL NO.1

Certification body in  
**telecommunications** and  
**Automotive** sector

## TOP 3 IN THE UK

ISO 9001, ISO 14001,  
ISO 45001, ISO 27001

## GLOBAL NO.3

Certification body in  
**Aerospace** sector

## CHINA'S NO.1

Certification body in  
**Automotive** sector

## UK'S NO.2

Certification body in  
**Aerospace** sector



NEVER STOP IMPROVING

# 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



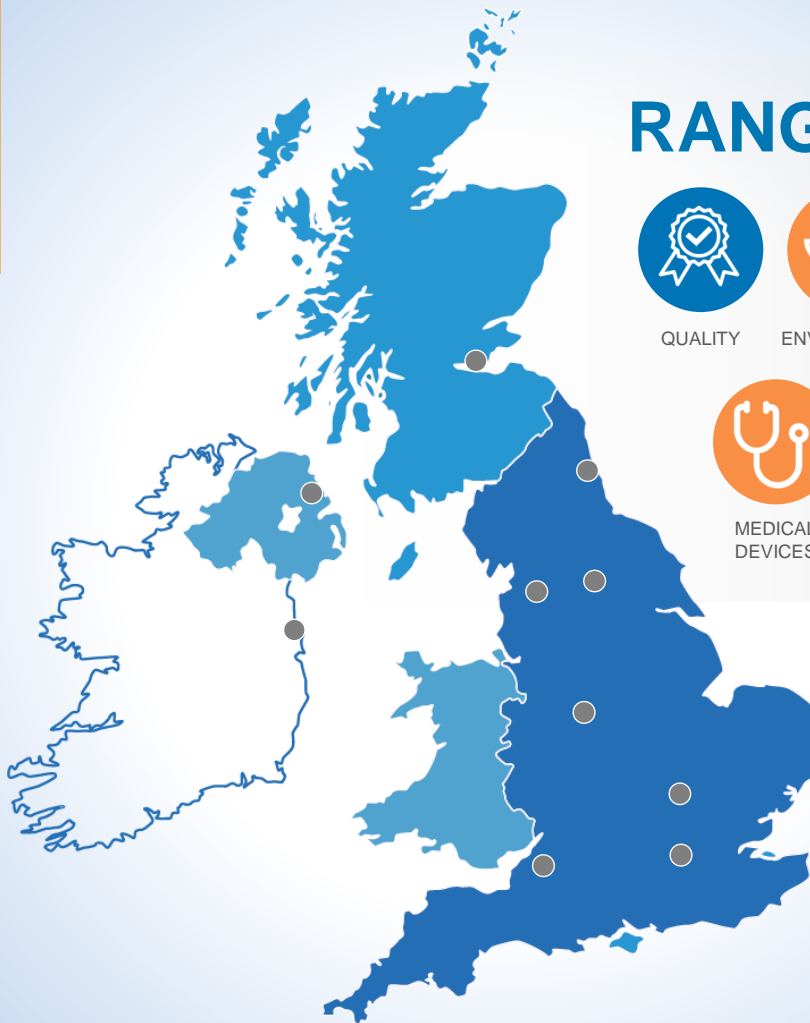
e-Learning /  
Live Webinars



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

 CQI |  IRCA  
APPROVED TRAINING PARTNER





NEVER STOP IMPROVING

## KEY INFO

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

## YOUR PRESENTER



### Martin Graham

ISO 9001, ISO 14001, ISO 45001,  
ISO 50001, SSIP

**NQA Principal Assessor for Quality**



Martin is an experienced lead auditor, with 20 years' exposure to the certification industry covering sectors including retail, manufacturing and assembly, construction, engineering, testing, mechanical & electrical installations, transport logistics, communication, education and training providers. Having knowledge of managing each step of the certification process, he is well positioned to understand clients' needs and support them through the certification process.

# WHAT WILL BE DISCUSSED?

- What is an internal audit?
- Audit objectives
- Programme
- Planning
- Outputs



# WHAT IS AN AUDIT?

---

# DEFINITION

---

***‘systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled’***

***ISO 19011:2018***

---



# DEFINITION

---

***Systematic – programmed, planned, under control***

***Independent – impartial, objective***

***Documented – does not mean you need a procedure***

---

# WHAT IS AUDIT CRITERIA?

---

# WHAT IS AUDIT CRITERIA?

---

Set of policies, procedures or requirements used as a reference against which objective evidence is compared.

Ref: ISO 9000:2015

e.g.:

- Policies
  - Objectives
  - Procedures
  - Standards
  - Contractual requirements
  - Statutory and regulatory requirements
-

# AUDIT OBJECTIVES – WHY DO AN INTERNAL AUDIT?

---



NEVER STOP IMPROVING

# WHY...

- Identify risks
- Identify opportunities
- Identify improvements
- Identify inefficiencies
- Spread the word
- Add value
- Support engagement
- Meet the standard!
- Why not...

# AUDIT OBJECTIVES

---

- Conformance with planned arrangements
  - Conformance with the standard
  - Effectiveness of the system
  - Not just to show a third party auditor...ensure you schedule, plan, execute, act and report to get value for your organisation
-

# OBJECTIVE EVIDENCE

---



NEVER STOP IMPROVING

# OBJECTIVE EVIDENCE

---

Objective Evidence is data (generally consists of records, statements of fact, or other information) supporting the existence or verity of something

Ref:

- ISO 9000:2015
- ISO 19011:2018

Can be obtained through review of documentation/records, observation, interview and following the audit trail

---



# OBJECTIVE EVIDENCE

Objective evidence is data (generally consists of records, statements of fact, or other information) supporting the existence or verity of something

You can collect evidence use the following methods

- Interviewing

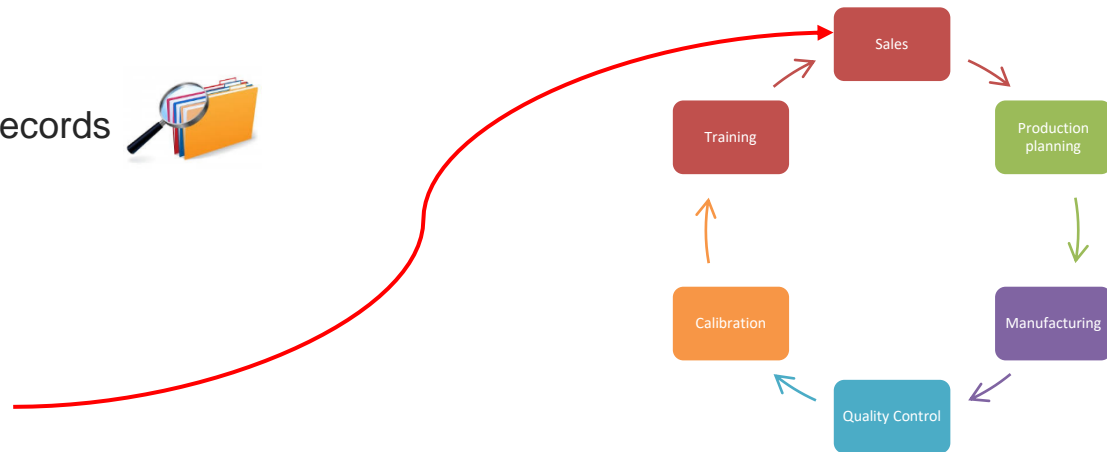


- Review of documents and records



- Observation

- Following the



# CLAUSE 9.2

---

## CLAUSE 9.2

---

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

- a) Conforms to:
    - 1) the organization's own requirements for its quality management system;
    - 2) the requirements of this International Standard;
  - b) Is effectively implemented and maintained
-

## CLAUSE 9.2

---

The organization shall:

- a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - b) define the audit criteria and scope for each audit;
  - c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
  - d) ensure that the results of the audits are reported to relevant management;
  - e) take appropriate correction and corrective actions without undue delay;
  - f) retain documented information as evidence of the implementation of the audit programme and the audit results.
-

# PROGRAMME

---

# PROGRAMME – SIMPLE BUT...

---

**frequency,**

**methods, (remote?)**

**responsibilities,**

**planning requirements and reporting,**

**shall take into consideration the importance of the processes concerned, (risk?)**

**changes affecting the organization, (people / process / material)**

**and the results of previous audits;**

---

## **Audit Programme to Consider:**

Auditees :

- Organisational Objectives
- Relevant external and internal issues
- The needs and expectations of relevant interested parties
- Information security and confidentiality requirements
- Locations and logistics
- Outsourced functions

**Note:** Changes to the programme should be monitored and maintained, revisions made when changes happen with findings disseminated to all relevant interested parties

---

# PLAN

---



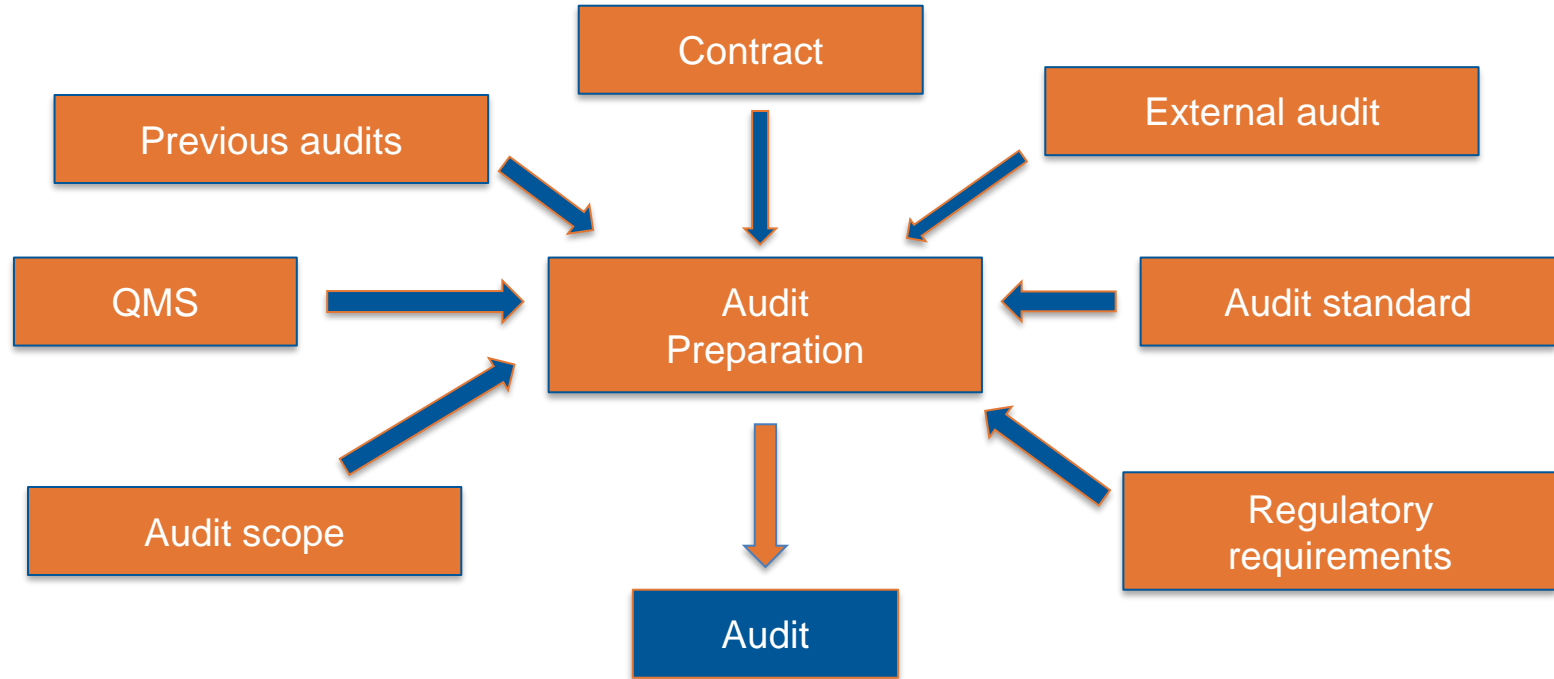
# PLAN – NOT A PROGRAMME

---

- Detail what you wish to audit (areas, documents, records and activities)
  - Who to select for interview
  - Where and when (locations, sequence, audit trails etc.)
  - What methods to use to obtain objective evidence (e.g. observation interview, review of documents and records etc.)
  - Communicate it
-

- 
- Agree dates / times and personnel availability
  - Agree scope and objectives
  - Obtain necessary procedures and associated documents
  - Familiarise yourself with the process to be audited
  - Prepare / obtain checklists
  - Prepare the team
-

# AUDIT PREPARATION - INPUTS



# EXECUTION

---

# EXECUTION - CHECKLISTS

---

- Professional approach
  - Ensures structured, thorough preparation
  - Acts as a guide/aide memoir
  - Provides evidence of what was planned and checked
  - Assists note taking
  - Assists preparation for reporting and the closing meeting
-

# EXECUTION - INITIATION

---

- Appointing a team leader
  - Establishing contact with the auditee and information gathering
  - Defining the scope, objectives and criteria
  - Selecting the audit team
-

# EXECUTION - PRINCIPLES

---

- Integrity: Auditors exhibit a “professional” approach
- Fair Presentation: Truthful and accurate reporting
- Due Professional Care: Exercising diligence and judgement
- Confidentiality: Security of information
- Independence: A basic impartiality and objectivity of conclusions
- Evidence-based Approach: The evidence is verifiable and based on appropriate sampling
- Risk-based Approach: an audit approach that considers risks and opportunities

# EXECUTION - OPENING

---

- Confirm the agreement of all participants (e.g. auditee, audit team) to the audit plan;
  - Introduce the audit team and their roles
  - Confirm the audit plan
  - Confirm scope and audit criteria
  - Confidentiality arrangements
  - Gradings of NCR's and findings
  - Communication channels
  - Confirm time, place and attendees for closing meeting
  - Invite questions
-






# EXECUTION - CLOSING

---

- Lead Auditor chairs the meeting
  - To include auditee (those responsible), management, audit team, interested parties (identified by client)
  - Introductions
  - Confirm the scope and objectives of the audit
  - Confirm audit standard and any exclusions
  - Statement of confidentiality & Disclaimer (audit was only a sample)
  - Summary of findings (including good points) effectiveness of the MS
  - Presentation of nonconformities and OFI's
  - Invite discussion of points raised
  - Explain corrective action process
-

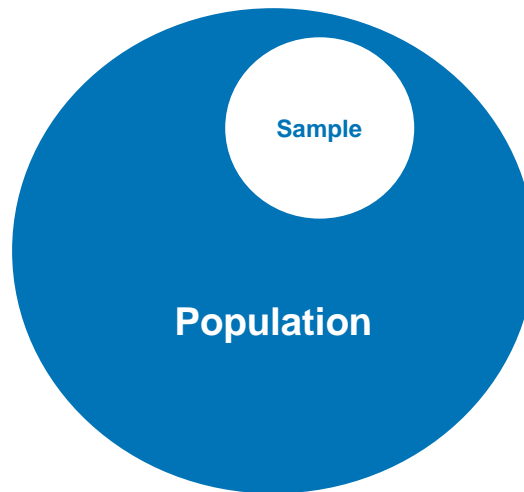
# THE 6 STAGE AUDIT PROCESS

Structure		6 Stage Approach	Key skills
Start		Set the scene 	• Build rapport
		Confirm the basics 	• Questioning • Listening • Understanding of the business
Middle		Establish the process 	• Listening • Probing • Understanding processes
		Search for evidence 	• Questioning • Sampling • Observation • Note taking • Time management • Evaluation of evidence
		Check back 	• Planning
End		Close out 	• Decision making • Feedback • Rapport

# SAMPLING METHODS AND TIPS

---

- What to sample?
- Risk factors to consider?
- How many samples to take?
- How far back in time?
- Who should take the sample?



# GATHERING EVIDENCE

---

- Take more than 1 sample
  - Link samples to an audit trail – follow the process
  - Do not let the auditee select the all the samples
  - The spoken word alone is not necessarily objective evidence of conformance
  - Respect the auditees documents
-

# QUESTIONING TECHNIQUES

---

- Think about the question before you ask it
- Keep your questions simple
- Do not start the audit with pre-conceived ideas or a 'hidden agenda'
- Speak clearly – avoid code or jargon
- Clarify any points of misunderstanding as soon as possible
- Give the auditee chance to explain
- Don't jump to hasty conclusions



# QUESTION TYPES

---

- Open
- Closed
- Multiple
- Leading

***“I kept six honest serving men, they  
taught me all I knew, their names are  
What and Why and When and How and  
Where and Who”***

Rudyard Kipling - The Elephant Child

---

# FINDINGS AND FOLLOW UP

---

## ‘Non-fulfilment of a requirement’

Ref: ISO 9000:2015

---



# NONCONFORMITY

---

**The 'requirement' in an internal audit situation will be the specific audit criteria which apply e.g.**

- Procedures = Operational issues
- Quality Manual = Management issues
- Standard = Policy issues
- Contract = Customer issues
- Legislation = Regulatory issues



# REASONS TO RAISE NON-CONFORMITIES

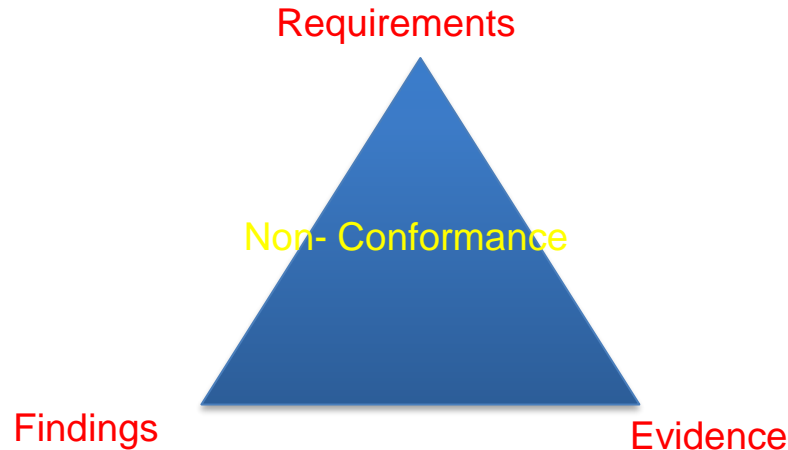
---

- Practice does not comply with the documented system
- The system does not reflect actual practice
- Practice/system does not comply with ISO 9001 (or applicable standard)
- Breach of a legal or other requirement
- Breach in commitment to continual improvement
- Breach in commitment to prevent pollution
- Breach in commitment to prevent ill health or injury
- Not meeting policy
- Not meeting intended outcomes



# DEFINING NON-CONFORMITIES

---



**The Non-Conformance ‘triangle’**



# OPPORTUNITY FOR IMPROVEMENT

---

- Opportunity to refine the system
  - May develop into a nonconformity
  - Should benefit the system / organisation
  - Don't have to be acted upon
-

# ACTIONS – CORRECTION AND CORRECTIVE

---

# CORRECTION & CORRECTIVE ACTION

---

- Correction - Action to eliminate a detected nonconformity
- Corrective Action - To eliminate the cause of nonconformities in order to prevent recurrence



# CORRECTION & CORRECTIVE ACTION

---

- When a nonconformity occurs, including any arising from complaints, the organization shall:
  - a) react to the nonconformity and, as applicable:
    - 1) take action to control and correct it;
    - 2) deal with the consequences;



# CORRECTION & CORRECTIVE ACTION

---

b) 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;





# CORRECTION & CORRECTIVE ACTION

---

- c) implement any action needed;
  - d) review the effectiveness of any corrective action taken;
  - e) update risks and opportunities determined during planning, if necessary;
  - f) make changes to the quality management system, if necessary.
- Corrective actions shall be appropriate to the effects of the nonconformities encountered.



# FOLLOW UP AND CLOSE OUT

---

- Verify effectiveness of actions and implementation
- Record examples of evidence seen
- Escalate if not addressed
- Agree new actions if not effective
- Close out nonconformity when cleared
- Feed back into programme / planning
- Management review



# KEEP IT SIMPLE

---

- Don't over plan
- Understand what an audit is for and what you are trying to achieve
- Keep record and act on results
- Communicate
- Get people involved
- Don't see an audit as negative



# Q&A

---



NEVER STOP IMPROVING

# TAKE THE NEXT STEP

---

The background of the main banner features a series of concentric circular targets in shades of blue and red, receding into the distance. Several white arrows with blue fletching are shown in flight, hitting the bullseyes of the targets.

## QUALITY MANAGEMENT

Discover how NQA can help you achieve your quality certification goals with an ISO 9001 training course.

▶ **Book your  
place here!**

---

# THANK YOU

Warwick House | Houghton Hall Park | Houghton Regis | Dunstable | LU5 5ZX | United Kingdom  
0800 052 2424 | [www.nqa.com](http://www.nqa.com)

---