

What's the Big Deal with ISO: An Intro to ISO Registration and Preparing to be Certified

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Randy Pittman works for National Quality Assurance USA (NQA-USA), an independent 3rd party certification registrar. For the past 8 years Randy has primarily served within the business development group, developing and delivering a unique customer service based consultant referral program for NQA clients. With a B.S degree in Geo Physical Science Randy began his career as an organic chemist for an environmental testing firm. Randy later returned back to the family business as a project manager which included logistics design and coordination for construction projects; both domestic and international. He has experience with risk management relating to ISO 31000 and business continuity methodologies. He volunteers his professional and quality management skills as the North East “Senior Director” for a national non-profit organization.

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What Is ISO?

- ISO 9001 is a set of international standards for management and verification of good quality management practices.
- ISO (International Organization for Standardization) is an international organization that certifies that businesses, government organizations and social entities meet certain common standards.

The name ISO was taken from the Greek "isos" meaning "equal," and is used without alteration in every language in all countries which participate.

What is ISO?

8 Quality Management Principals

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

Why All the Standards?

- **ISO 9001** (Quality Management)
- **AS9100** (Aerospace)
- **AS9110** (Aerospace Repair Depots)
- **AS9120** (Aerospace Distribution)
- **ISO 27001** (Information Security)
- **ISO 20000-1** (IT Svc. Management)
- **ISO 22000** (Food safety management)
- **TS16949** (Automotive)
- **ISO 6081/5553** (Counterfeit Parts)
- **TL 9000** (Telecommunications)
- **ISO 14001** (Environmental Management)
- **ANSI/ESD S20.20** (ESD Control)
- **OHSAS 18001** (Occupational Health & Safety)
- **ISO 13485** (Medical Devices)
- **PS-Prep** (Private Sector Preparedness)
- **VCAP** (Verified Conformity Assessment)
- **ISO 28000** (Security in the Supply Chain)

Is Getting ISO Certified Right for You?

Benefits of Registration

- Customer/3rd party assurance
- Reference documents
- Consistency
- Management confidence
- Training
- Knowledge retention
- Base for improvement

Is Getting ISO Certified Right for You?

Improvements with ISO 9001 QMS Implementation

- Effective Management Control
- Process efficiency
- Productivity and Quality consistency
- Internal communication
- Supplier control
- International Recognition
- Repeat sales and Increased market share
- Customer satisfaction (both Internal and External)
- Staff morale and motivation

Is Getting ISO Certified Right for You?

What does ISO 9001 MS help reduce?

- Customer Complaints
- Costs
- Waste
- Duplication of effort
- Staff turnover
- Supplier problems

How to Prepare for Registration

- Gain Management Commitment
- Select a Management Rep./Consultant
- Get a copy of the standard
- Complete a GAP analysis
- Select a Registrar
- Management Training
- Create a Quality Manual/Quality Policy
- Determine Process Owners
- Create Required Procedures
- Document Necessary Processes through work instructions
- Create forms that record data as evidence of compliance
- Audit for Compliance
- Phase 1: Document Audit
- Phase 2: Final Assessment

How to Prepare for Registration

Management Commitment

This point may seem obvious - but the biggest obstacle quoted by a Registrar is:

Management buy-in and support

How to Prepare for Registration

Management Commitment starts at the top

- Letter from highest authority giving management representative permission to implement the system.
- Kick off meeting by the highest authority to inform everyone who the Management Representative is and what ISO entails.

How to Prepare for Registration

Make the project inviting

- Employees won't want to get involved on the project unless they know what it means to them and to their job.
 - Explain why ISO is important to the company
 - Explain how it will make their job easier.
 - Explain how their job will be different
 - *And* how it will be the same.

How to Prepare for Registration

Understand that employees may feel threatened.

- “If I document everything I do, will I still have value?”
- “What is this corrective action? It sounds like going to the principals office.”
- “Someone is going to audit my performance?”

How to Prepare for Registration

Remove the threat

- Involve Employees in the development process.
 - Managers/Supervisors should own the process and have initial approval of all changes.
 - As process owners develop processes to meet the standard and should include the people that are currently involved in the process.
 - Train all staff on the corrective action and internal audits; emphasize the focus on improving the process.

How to Prepare for Registration

Select a Management Rep./Consultant

- The standard requires that the MR must be "a member of management" serving primarily as the "eyes" and "ears" of top management to monitor how well the quality system is developed and implemented.
- The MR primarily provides feedback to top management on the effectiveness of the quality management system.

How to Prepare for Registration

Management Representatives Responsibility

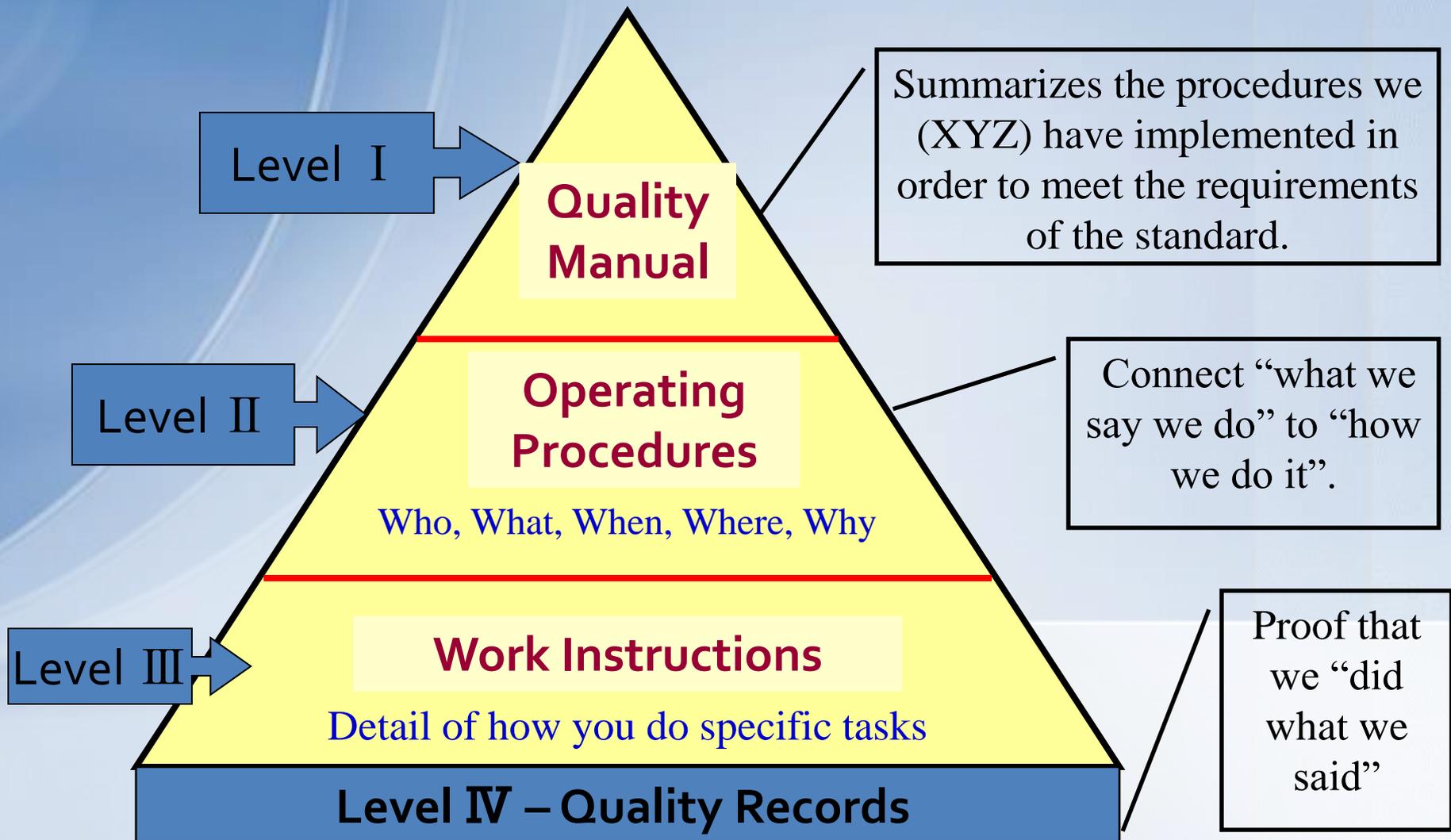
- Ensuring implementation and compliance to the standard.
 - Document Control
 - Training
 - Project Manager
- Reporting Results
 - Facilitator for Management Review
 - Manages Internal Audit Cycle
 - Tracking open issues
- Ensure Awareness
 - Ensure that customer requirements are communicated
 - Ensure employee awareness
- Quality Liaison

How to Prepare for Registration

Key Characteristics

- Strong knowledge of ISO 9001 requirements
- Coach/Teach/Team Leader
- Self Motivated
- Project management and organizational skills
- Ability to listen and influence
- Ability to summarize information and communicate effectively
- Uses the KISS approach to documentation

Required ISO 9001 Documentation



How to Prepare for Registration

QUALITY MANUAL

Do

- Keep it simple and concise- shoot for minimum number of pages is the goal.
- Make it useful as a Sales Tool
- Quality Manual has only three requirements
 - Scope of the quality management system, including justification of exclusions
 - Reference to the documented procedures
 - Describe the interactions between processes

How to Prepare for Registration

QUALITY MANUAL

Do not

- Write the great American novel
- Reiterate the ISO 9001 standard
- Cover items already covered in the procedures
- List procedures with revision
- List names of people, rather use function or job titles

How to Prepare for Registration

Required Procedures

- Document Control
- Control of Quality Records
- Control of Nonconformities
- Corrective Actions
- Preventive Actions
- Internal Audits

How to Prepare for Registration

Procedures

Do

- Establish Process Owners(PO)
- Provide ownership to the PO
- Train every two years

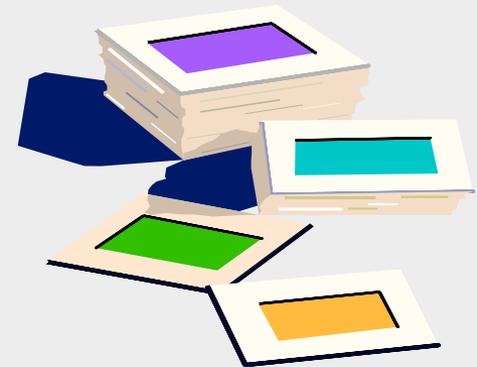
Don't

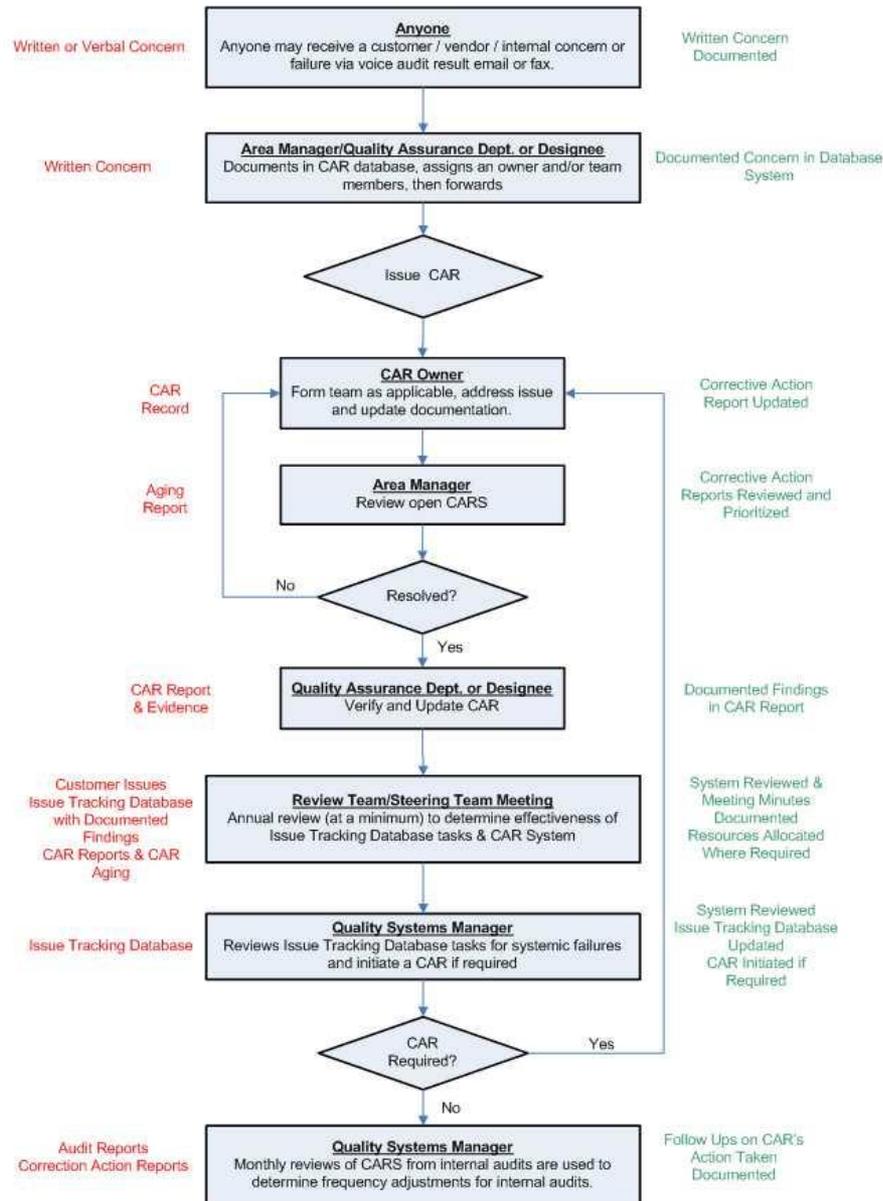
- Establish 100's of procedures more than 20 is a waste
- Keep procedures or work instructions that are not used

How to Prepare for Registration

Work Instruction

- Detailed instructions on how to complete a process.
- Any format
- Requirements:
 - Title name,
 - revision,
 - date implemented





How to Prepare for Registration

Why Audit?

- To verify the adequacy and adherence to stated requirements. Implementation is the key to managing the Quality System.
 - **Allows for measurement of results.**
 - **Allows for consistency and reproducible results.**
 - **Allows for process improvement initiatives.**
- Implementation – ***“Say what you do, do what you say”***

How to Prepare for Registration

Internal Audits

- Select auditors wisely
- Auditors can not audit their own work
- Use audit checklists to ensure consistency
- Combine requirements to reduce the number of audits
- When collecting evidence documents or records trump verbal.
- Inform process owner of findings as they happen
- Include top management in report out
- Report internal audits in management review
- Combine Internal Audit findings with Corrective and Preventive Action System

How to Prepare for Registration

Internal Audit Flow



Steps to Registration

- The NQA audit program includes a two stage registration audit process followed by surveillance audits, and ultimately a recertification audit.
- NQA audits include on-site assessments of documents, data, records, activity and personnel. Process audit trails are followed by interviews of personnel responsible for the tasks and reviewing associated activity and records of occurrence. The audit trail will follow interactions between processes as well as the details of the process itself. Following are the stages of the audit process.

Steps to Registration

Pre-assessment (Optional)

- The pre-assessment audit is an optional activity, outside of the registration process, that NQA highly encourages any organization to undertake to evaluate the readiness to undergo the two stage registration process.

Steps to Registration

Registration Audit - Stage 1

- The stage 1 audit, conducted at your facility, is primarily performed for planning and determining the readiness of an organization to undergo a stage 2 registration audit. It also facilitates communicating needs and expectations to the organization.

Steps to Registration

Registration Audit - Stage 2

- The objective of the Stage 2 on-site audit is to assess your organizations' adherence to your own policies, objectives, and procedures and to ascertain conformance to the requirements of the ISO 9001 standard. To accomplish this, the audit will address the implementation of all the elements of the standard.

Steps to Registration

Certificate Issuance

- Following a successful review of the audit team's report and associated corrective action submittal, NQA will authorize issuance of a certificate that is valid for a period of three years. The organization can expect to receive its certificate within 1-2 weeks of review and acceptance of corrective actions.

Preparation for Stage 2 audit:

- Complete one cycle of internal audits.
- Complete one management review.
- Have approximately 3 months of records.
- Have a minimum of one design project documented start to finish.
- Inform all employees aware of the audit.
- Let them know what to expect.
- Do a “Sweep” of your facility for uncalibrated equipment and uncontrolled documents.

Stage 2 - the purpose of this visit is to confirm that the quality management system fully conforms to the requirements of ISO 9001:2008 in practice. The Assessor will:

- perform sample audits of the processes and activities defined in the scope of assessment
- document how the system complies with the standard
- report any non-compliances or potential for non-compliance
- produce a surveillance plan and confirm a date for the first surveillance visit
- If the Assessor identifies any major non-conformance, the organization cannot be certified until corrective action is taken and verified.

Enjoy Your Success!

