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QUALITY REVIEW

A Newsletter for Quality Management Professionals

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IN THIS EDITION

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ISO 9001:2015 Clause 7 - Support

By Jim Moran, BRC Quality Consultant

In our last article we looked at ISO 9001:2015's Clause 6: Planning.

"If you fail to prepare, you are preparing to fail."

- Benjamin Franklin.

And Deming, of course, based his structured approach for quality on the PDCA model. Shewart was right in there, too. Now we'll take a look at another one of the requirements that will support our processes – **Clause 7: Support.**

Since we all need 'resources' to make any process produce outcomes, this requirement is no surprise whatsoever. We've been audited for 'adequate resources' for 27 years now, and nothing has changed, really. Just a few twists in the language, like 'knowledge'.

We see outsourcing mentioned here. Makes sense – why not consider all the possibilities in one section rather than having them spread out over a number of different procedures? After all, outsourced goods and services are becoming more and more prevalent.

Another interesting tweak here is the use of the phrase, 'existing internal resources, capabilities and limitations'. We are glad to see the use of the term 'capabilities' to remind us to assess our process capabilities while reviewing customer needs and expectations. It's always tempting to say, "Let's get the business first, and then try to figure out how to deliver it". None of OUR readers have ever thought this way, but many of us know some suppliers who do this!

Just as we saw in the 2008 version, we have to provide a suitable infrastructure with the right work environment to 'assure conformity of goods and services and customer satisfaction'. Pretty much what we'd expect.

Now here's an interesting new emphasis on what we've seen previously as the 'Process Approach', one of the 8 Management Principles. The new Standard pushes a bit harder on this concept.

We have to 'determine, provide and maintain the process environment necessary for its operations and to assure conformity of goods and services and customer satisfaction'. We really like the way they have emphasized the focus on processes leading to customer satisfaction. That's got to be a good move – the more emphasis on 'process' the better, in my opinion. Calibration is included in here, too – nothing really new, except the inclusion of customer surveys as a measurement device (Note 1).

'Knowledge' is a new term, separate from 'Competence', sub clause 7.2, so we'll need to review our use of these words to make sure we haven't missed any inferred requirements. We also see the use of that new term 'documented information' with regard to training or other interventions. Furthermore, we now have to ensure that our employees can demonstrate 'Awareness' of the Quality Policy and Objectives as well as each person's impact on quality. We can hear the phrases from ISO 14001 and OHSAS 18001 (and others) echoing through this clause.

'Communication' rounds out this section of requirements, and we can use whatever was relevant from the 2008 version around 5.5.3, Internal Communication. The clause ends with a description of the requirements around 'Documented Information'. It's exactly what we would expect and are already doing for our current Document Control and Control of Records.

No new requirements here but the requirement to 'identify changes' has been removed! This will save a ton of anguish and wasted effort on the part of QMRs trying to meet this antiquated idea. Current software has features to compare versions that can meet even the 2008 requirement.

One last note on 'Documented information'. There are a number of requirements to have documented information, but 'Procedures' is not one of them. **There are no requirements in this draft to document any procedures,** just like ISO 14001 and OHSAS 18001.

We see the same wording here for '...documented information determined by the organization as being necessary for the effectiveness of the quality management system.' We suspect this won't reduce 'management by the pound' (the more procedures the better) but we hope it will make organizations start to think about the power of training and how it can reduce the need for documented procedures.

A binder never saved a life – people save lives, training saves lives, but not binders. We would never see a fire fighting crew hop off of a pumper and yell, "Where's the binder that shows us how to hook this hose up to the pump?!?".

"Train, train, train and train some more."

– W. Edwards Deming

ISO 9001:2015 - Practical Leadership

By: Michael Haycock, Sr. BRC Quality Consultant

"True *Freedom* is not the absence of structure but rather a clear structure which enables people to work within established boundaries in an autonomous and creative way."

- Rosabeth Moss Kantor

Of the many books that have been written about Quality, very few have actually been attributed to women. That is both unfortunate and a loss. I have (and have actually read) several of Rosabeth Moss Kantor's books, and while she does not use a Quality mantra - her message, thoughts, philosophy and writing have been about management and change management within organizations.

They are also about the structure and functioning of organizations for them to be successful – and the leadership that is necessary to give any organization the chance to be successful. While she sees the same issues, concerns and challenges as the rest of us (and on which "Quality" gurus make a fortune) – her perspective is different. Her approach is solid – and real. She is a "good" read.

I used a line from a book as an introduction because we will try to bring a perspective on the new requirements around leadership. Once again we want you to do something that is practical – that means you can get done what is necessary without months of expensive training that will focus on a narrow segment of the organization. Leadership allows and provides the encouragement that you can and should, and will include most (if not all the organization) in the understanding and application of the system within their area of responsibility. The value to the organization will be obvious. That means you should have training – but training that is clear, easily understood and necessarily can be "practically" applied.

Examples are provided for organizational structure in section 4.1 (Note 1 – external, note 2 - internal), and detail of Leadership requirements in section 5. The standard is actually asking us to understand the environment in which we live. Environment may include the "green" part of our world but in this context more specifically the "social, cultural, legal, regulatory, technological, financial, natural and competitive" environment in which we must operate. A Quality management system (ISO) is a tool that does not, can not, work the same for all organizations in all situations – OF COURSE! So while the standard is the same around the world (and down the street), the application should be suited to the individual organization.

The expectation is that management will be clear (as possible) about the nature of the organization and how best to operate – to be successful. Some of this knowledge will be immediately obvious. Some of this knowledge can only come through trial and error. There is also a need to recognize that success is never permanent and the next challenge is just over the horizon.

The System based on ISO 9001:2015 should be integrated within the organization – not an add on. That doesn't mean environment, health and safety, finance, etc, are not different and require their own specialists. Of course they are – but the processes within the organization can be managed to allow for the differences but accommodate the common goals needed for success in the organization.

Leadership is different than management – both in involvement and commitment. Leadership is the ultimate mechanism that brings strength and direction. Leadership is asking you to walk on broken glass…and then walking with you.

My experience when helping with internal audits - it was extremely rare that any senior management would show up for closing meetings. When they did attend, almost without exception, there was an expression of the value in what was learned. (This lends itself most appropriately when the Internal audits were/are done once or maybe twice a year – so the strength of the system can be shared with management at that time.) Top or senior management must be helped to understand the value of the work being done.

My initial audit experience was with registration audits and management was expected (forced) to be present as an indication of commitment. (I know, I know.) It always seemed to me that with an internal audit, you are telling yourself about yourself, and this would be even more important. With the new emphasis on risk, the system (based on the standard) should be practical as well as important for management. Internal audits are the tool to help understand actual compliance to management specified and supported organizational activities.

Risk comes from many sources. From an audit perspective, risk comes from having a defined system where the organization has agreed to carry out certain activities in a prescribed manner – and then not doing so. Based on the Risk, this then lends itself to correction (fix the problem), corrective action (get to the root cause of the problem) or as organization and customers change – change the system to suit. What is important to top management is most typically what is important to people within the organization. Leadership will make it so.

Section 5, Leadership in the standard specifically addresses “Top Management”. As a little aside, we have been fortunate to work with many of you, who although may not specifically be considered Top Management, are undoubtedly leaders. We encourage you to continue your work in those roles.

Eagles fly into storms.

Ask the Expert
with Ted Uffen

Question:

What is the proper ITP signing process from all parties?

Do we only sign as the tasks are completed? Some client's are asking us to sign before hand.
Any info would be greatly appreciated.

Thank you.

- Denis Theriault, QA Coordinator, Maritime Welding

Answer:

ITPs – Inspection & Test Plans – need to be signed as tasks are completed, in order to accurately reflect the inspection status of the work undertaken. The only time a client normally has input into the signing process is at presentation of the product for acceptance by the customer’s inspector.

At that stage, you should have conducted your final inspection prior to presentation to the customer. If, at this point, the documents are not signed, the customer will interpret that to mean that final inspection has not been done, and the product is truly not ready for presentation.

I used to work for the Canadian Department of National Defence Quality Assurance Division. Contractually, signed copies of the release documents – CF1280, DD250, etc. – were to be signed prior to presentation for this precise reason. If they were not signed, no inspection or release of product occurred.

Hope this helps.

- Ted Uffen, BRC Quality Consultant

Audit Scenario

"Providing Resources"

From Lynn Clyde, BRC Consultant

The following is a typical auditing scenario that might be found when auditing an ISO 9001:2008 quality management system for clause 6.1 Provision of Resources. Read the scenario to determine if you think it would be conforming or nonconforming, then read the answer and explanation.

Support Information - ISO 9001:2008 Clause 6.1

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

Scenario

When interviewing the operations manager, the auditor asked to see evidence of determining and providing resources for the quality management system. The operations manager said this is done as part of the management review meetings.

Upon reviewing the minutes of the last meeting, the auditor noticed that there were no resources identified. The manager said "as you can see here in the minutes, it says we determined that no resources were necessary for this year". The auditor said that resources should always be required for the quality management system and this would be written as a non-conformance.

Answer

Conforming to Clause 6.1a.

Explanation

This clause requires that the organization determine whether or not resources are required. If it is determined that resources are required, they shall provide them. Resources may be determined in many ways: strategic planning, budgeting, production planning, project planning, quality planning and management review, to name a few.

Evidence may be shown by reviewing the documents or minutes of meetings.

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Highlights the requirements of the ISO 14001:2004 standard and delivers an understanding of what is involved in a practical, working Environmental Management System in any business environment. Click Here for Full Course Details Online

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ISO 14001:2004 Internal Auditor — 2 Days — $945

A review of the ISO 14001:2004 standard followed by in-depth instruction on the skills and techniques required to participate as a member of an auditing team. Combines presentations and case studies with individual and group exercises to teach the skills required to perform internal quality and environmental audits. This course adheres to ISO 19011:2011 guidelines for the auditing of management systems. Click Here for Full Course Details Online

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May 28 - 29 .....Guelph, ON
May 28 - 29 .....Halifax, NS
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Additional Environmental Management Courses (Available On-Site)

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Understanding & Implementing CSA Z1000-06 — 2 Days — $945

Provides a detailed overview of the requirements of CSA Z1000-06, Canada's National Standard for occupational health and safety management. Attendees will develop a solid understanding of how to create an effective policy for health and safety in their organization. Click Here for Full Course Details Online

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CSA Z1000-06 Internal Auditor — 2 Days — $945

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Understanding Integrated ISO 9001 / 14001 / 18001 — 2 Days — $995

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AS9110 Rev. B Internal Auditor - 2 Days

Understanding AS9120 Rev. A - 2 Days

AS9120 Rev. A Internal Auditor - 2 Days

AS 9100 Rev. C Risk Management - 2 Days

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Understanding & Implementing TS 16949:2009 — 2 Days — $995

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TS 16949:2009 Internal Auditor — 2 Days — $995

A review of the TS 16949:2009 standard followed by in-depth instruction on the skills and techniques required to participate as a member of an auditing team. Combines presentations and case studies with individual and group exercises to teach the skills required to perform internal quality audits. This course adheres to ISO 19011:2011 auditing guidelines and emphasizes the Process Approach to auditing. Click Here for Full Course Details Online

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Core Tools (FMEA, MSA, PPAP, APQP, SPC) — 2 Days — $995

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FMEA (Failure Modes and Effects Analysis) – Intermediate Level — 2 Days — $995

Detailed instruction on FMEA, a team-based risk management technique that recognizes and evaluates the potential failure of a product or process and identifies actions that could eliminate or reduce the chance of the failure occurring. This course will help participants acquire the knowledge and skills necessary to understand and interpret the FMEA 4th Edition guideline requirements and to develop and implement FMEAs within their company's automotive manufacturing operations.
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Additional Automotive Courses (Available On-Site)

8D Problem Solving (1 Day)

MSA (Measurement Systems Analysis) (2 Days)

SPC (Statistical Process Control) (1-2 Days)

APQP (Advanced Product Quality Planning) (1 Day)

APQP & PPAP (1 Day)

APQP, FMEA, Control Plan & Error Proofing (3-4 Days)

TPM (Total Productive Maintenance) & Set-Up Reduction (1 Day)

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Understanding & Implementing ISO 13485:2003 — 2 Days — $995

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ISO 13485:2003 Internal Auditor — 2 Days — $995

Provides participants with an understanding of the ISO 13485:2003 standard and requirements and establishes basic auditing principles. Through workshops and exercises participants will learn to interpret the ISO 13485 requirements for their own company, as well as plan and conduct internal and supplier audits. Click Here for Full Course Details Online

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ISO 13485 & Title 21 CFR Part 820 - 2 Days

Understanding ISO 14971:2007 (Risk Management) - 1 Day

Understanding ISO 14971:2007 & Title 21 CFR Part 820 - 1 Day

CMDR (Canadian Medical Device Regulations) & ISO 13485 - 1/2 Day

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Ensures an understanding of the ISO 17025:2005 standard and provides clarity and guidance on the steps required to implement a Quality Management System in a testing and/or calibration laboratory. Click Here for Full Course Details Online

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Jun. 15 - 16 .....Victoria, BC
Jun. 25 - 26 .....Guelph, ON
Jun. 25 - 26 .....Burlington, ON
Jun. 25 - 26.....Mississauga, ON

Additional Testing & Calibration Courses (Available On-Site)

Measurement of Uncertainty (1 Day)

Click Here for More Details and to Request a Quote

AUDITING & QUALITY SKILLS

Advanced Auditing Skills — 2 Days — $995

A more in-depth auditing course for experienced auditors, "Advanced Auditing Skills" quickly refreshes the fundamental auditing skills and then goes on to cover the knowledge and skills required to lead an audit team. Participants receive instruction on how to plan an audit program, select and manage an audit team, conduct opening and closing meetings, prepare audit reports and findings, and effectively identify opportunities for improvement. Click Here for Full Course Details Online

Feb. 10 - 11 .....Burlington, ON	**Apr. 7 - 8** .....Saskatoon, SK	**May 28 - 29** .....Mississauga, ON
Feb. 10 - 11.....Guelph, ON	**Apr. 23 - 24** .....Victoria, BC	**Jun. 16 - 17** .....Calgary, AB
Feb. 11 - 12 .....London, ON	**May 21 - 22** .....Halifax, NS	**Jun. 16 - 17** .....Edmonton, AB
Mar. 24 - 25 .....Edmonton, AB	**May 27 - 28** .....Saint John, NB	**Jun. 16 - 17**.....Ottawa, ON

Root Cause Analysis — 2 Days — $945

This course covers the Root Cause Analysis method of problem solving that focuses on solving problems by identifying and correcting the root cause(s), as opposed to treating the symptoms. Participants will receive an overview of problem solving techniques and approaches, as well as detailed instruction on the different tools and techniques used as part of the Root Cause Analysis approach. Click Here for Full Course Details Online

Jan. 29 - 30 .....Burlington, ON	**Mar. 19 - 20** .....Saskatoon, SK	**Jun. 1 - 2** .....Edmonton, AB
Jan. 29 - 30.....Guelph, ON	**Mar. 24 - 25** .....Halifax, NS	**Jun. 9 - 10**.....Belleville, ON
Jan. 29 - 30 .....London, ON	**Apr. 13 - 14**.....Winnipeg, MB	**Jun. 9 - 10** .....Ottawa, ON
Feb. 5 - 6 .....Mississauga, ON	**May 6 - 7** .....Victoria, BC	**Jun. 9 - 10** .....Scarborough, ON
Feb. 19 - 20.....Edmonton, AB	**May 14 - 15** .....Saint John, NB	**Jun. 11 - 12** .....Guelph, ON
Feb. 26 - 27 .....Belleville, ON	**May 20 - 21** .....Windsor, ON	**Jun. 11 - 12** .....Mississauga, ON
Feb. 26 - 27.....Scarborough, ON	**May 24 - 25** .....Sudbury, ON	**Jun. 18 - 19** .....Calgary, AB
Mar. 9 - 10 .....Calgary, AB	**Jun. 1 - 2** .....Winnipeg, MB	**Jul. 6 - 7** .....Halifax, NS
Mar. 17 - 18 .....Ottawa, ON		

Process Mapping — 2 Days — $995

This course will provide the participants with an understanding of what a process is and how to define it. Participants will use real life problems to learn the practical techniques required to develop Process Maps and how to use Process Mapping as a tool for process analysis and improvement. Click Here for Full Course Details Online

Feb. 5 - 6 .....Mississauga, ON	**Apr. 7 - 8** .....Calgary, AB	**Jun. 27 - 28** .....Halifax, NS
Feb. 24 - 25 .....Ottawa, ON	**Jun. 1 - 2** .....Edmonton, AB	

Additional Auditing & Quality Skills Courses (Available On-Site)

Fundamental Auditing Skills - 1 Day

Introduction to Root Cause Analysis - 1 Day

ISO 19011 & The Process Approach to Auditing - 2 Days

Quality Assurance Auditing & Risk Management - 2 Days

8D Problem Solving - 1 Day

Basics of Problem Solving & Continual Improvement - 2 Days

Process Mapping, Problem Solving & Continual Improvement - 2 Days

Layered Process Auditing - 2 Days

Measuring Customer Satisfaction - 1 Day

Quality Improvement - 2 Days

Second Party Auditing Skills - 2 Days

Click Here for More Details and to Request a Quote

MANUFACTURING SERVICES

FMEA (Failure Modes and Effects Analysis) – Intermediate Level 2 Days $995

Detailed instruction on FMEA, a team-based risk management technique that recognizes and evaluates the potential failure of a product or process and identifies actions that could eliminate or reduce the chance of the failure occurring. This course will help participants acquire the knowledge and skills necessary to understand and interpret the FMEA 4th Edition guideline requirements and to develop and implement FMEAs within their company's automotive manufacturing operations.

Click Here for Full Course Details Online

Mar. 26 - 27.....Winnipeg, MB
Apr. 27 - 28.....Scarborough, ON
Apr. 29 - 30 .....Guelph, ON
May 28 - 29 .....Windsor, ON

Additional Manufacturing Courses (Available On-Site)

8D Problem Solving - 1 Day

Understanding 5S - 1 Day

GD&T - 2-3 Days

Lean Six Sigma Executive Overview - 1/2 Day

MSA (Measurement Systems Analysis) - 2 Days

SPC (Statistical Process Control) - 1-2 Days

APQP (Advanced Product Quality Planning) - 1 Day

APQP & PPAP - 1 Day

APQP, FMEA, Control Plan & Error Proofing - 3-4 Days

TPM (Total Productive Maintenance) & Set-Up Reduction - 1 Day

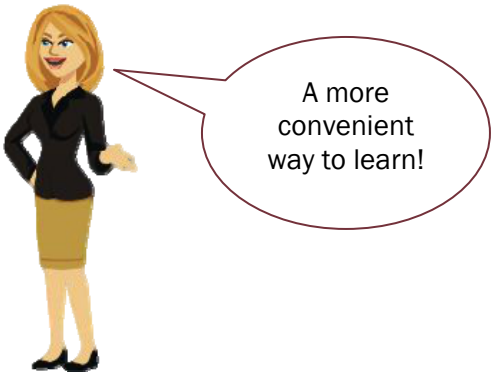
DoE (Design of Experiments) - Introduction - 3-4 Days

Value Stream Mapping (Introduction) - 1 Day

Click Here for More Details and to Request a Quote

ONLINE TRAINING

Online Training is HERE!



ISO 9001:2008 Essentials - Online Training ($129)

The ideal way to expand your organization's understanding of Quality Management and ISO 9001:2008, as well as to communicate the associated responsibilities and benefits.

This online course uses animated and interactive content to provide an introduction to the world of ISO 9001:2008. Through this independent, on-demand training, participants will gain an understanding of the history, principles and fundamentals of Quality Management, Quality Management Systems, and the ISO 9001:2008 standard itself.

Animated & Interactive

Videos

Quizzes

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MANAGEMENT SKILLS

Management Development - Level I

Designed for new managers looking to develop their skills to more effectively manage time & people. These 1 Day, on-site courses include group instruction and workshops, and can be shortened to 1/2 Day seminars and combined for broader training.

How to Succeed as a Manager

Learn communication skills & strategies, personal organization techniques, approaches to problem solving, how to take control of the work day / place, and tips for boosting productivity.

Ideal for aspiring, new or current managers with no formal training.

View Full Course Details Online

Effective Communication in the Workplace

Understand the principles of effective communication and its impact in the workplace, and practice real strategies for persuading, negotiating and communicating effectively.

Designed for managers, but beneficial to employees at all levels.

View Full Course Details Online

Dealing with People (Difficult or Otherwise)

Understand the types of difficult people and their motivations, learn to manage your reactions, & develop goals/strategies for overcoming negativity and getting results from team members.

Beneficial for managers and employees at all levels of experience.

View Full Course Details Online

Taking Control of Time and Priorities

Learn to take control of the work environment by planning your day, prioritizing tasks, delegating to other and limiting distractions.

Impactful training that will boost the productivity of managers, administrators and busy employees.

View Full Course Details Online

Management Development - Level II

Designed for experienced managers looking to cultivate their corporate culture and maximize leadership skills. These 1 Day, on-site courses include group instruction and workshops, and can be shortened to 1/2 Day seminars and combined for broader training.

Effective Leadership Skills

Understand the skills and values of great leaders and learn to build relationships, lead diverse groups, manage change & align priorities with your organization's strategic direction.

A higher level of training for managers looking to become leaders.

View Full Course Details Online

Developing and Motivating Effective Teams

Learn the characteristics and skill-sets of productive teams, and the keys to managing team growth and development.

For experienced leaders charged with the responsibility of keeping teams, and the organization, working effectively.

View Full Course Details Online

Managing Workplace Conflict

Go beyond the individual relationship and understand how conflict impacts the workplace.

Learn how to constructively address problem behaviour, deal with team emotions and dynamics, and model appropriate conduct.

View Full Course Details Online

Successfully Managing Change

Understand the forces behind organizational change & the impact it can have on employees, customers & stakeholders.

Experienced leaders will learn plans, strategies & actions for developing resilience & guiding people through change.

View Full Course Details Online

Project Management

For professional project managers or employees in a matrix or project environment, these courses present best practices to plan and run projects to ensure successful delivery and stakeholder satisfaction.

These courses may be applied toward the education/training requirements of the CAPM or PMP certifications.

Introduction to Project Management (1 Day)

Understand the basic fundamentals, tools and concepts required to plan, manage and close a project, including structure, scheduling, costs, communication, risk and other elements.

View Full Course Details Online

Intermediate & Advanced Project Management

Designed for participants with introductory knowledge, this course material follows the Product Management Body of Knowledge as is tailored to your specific needs.

View Full Course Details Online

OTHER COURSES

Oil & Gas

Understanding & Implementing API Spec Q1 - 2 Days

Emergency Management

Comprehensive Emergency Management (2 Days)

Food Safety Management

Understanding & Implementing ISO 22000:2005 (1 Day)

ISO 22000:2005 Internal Auditor (2 Days)

Risk Management

Understanding ISO 30001:2009 (1 Day)

Energy Management

Understanding ISO 50001:2011 (1 Day)

Configuration Management

Understanding ISO 10007:2003 (1 Day)

OTHER SERVICES AVAILABLE FROM THE BRC

(Click on a topic to learn more...)

Online Training

Cutting edge and interactive.

Train from anywhere on your schedule, and reach more employees than ever before.

Learn More

Consulting

Leverage our expertise, tools and resources to improve your systems, solve problems, and put the puzzle pieces together.

Learn More

Auditing

Internal, 2nd and 3rd party audit services by our qualified team.

Affordable and professional, our focus is on delivering value.

Learn More

Systems Implementation

Professional assistance with developing and implementing your management system.

Learn More

Documentation

Get experienced help with the creation, simplification or revision of polices, procedures and other documents.

Learn More

QMS Management

A cost-effective way to manage your system. We do the heavy lifting so you don't have to.

Learn More