

# BONZA NEWS

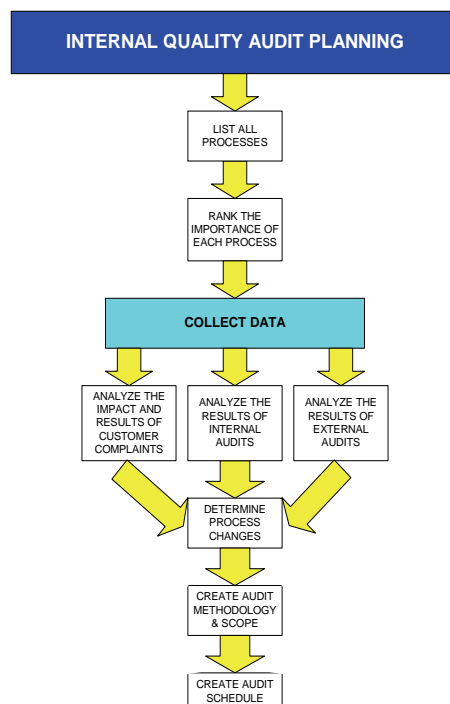
## Internal Quality Audit Planning

By Mark J. Magda

Internal quality audits are an important function of every organization's quality system. Vital information is extracted when the organization's quality system and processes are audited on a prescribed basis. Planning is the first and most important step before audits are performed.

There is one very important factor to consider when planning your internal audits. Section 8.2.2 of the ANSI/ISO/ASQ Q9001-2008 states, "an audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits." Simply stated, the internal quality audit function must define a methodology for determining what, when, why, and how often the processes and elements of the organization are audited. The best way to accomplish this is through a structured approach to audit planning. Proper audit planning establishes a formal sequence of events, where each event adds merit and credibility to the audit function. Planning also provides you with a formal documented methodology, which becomes a very important and powerful auditing tool (refer to Fig. #1).

FIGURE #1



### QUOTE

“When planning for a year, plant corn. When planning for a decade, plant trees. When planning for life, train and educate people.”  
– Chinese Proverb

### GOOD NEWS

#### Health Canada Endorses ISO GMP Standard

The standard on Good Manufacturing Practices (GMPs) for Cosmetic Products, which was adopted by the International Standards Organization (ISO) in 2007 has just been endorsed by Canadian authorities. In order help cosmetics makers to meet Canadian safety and quality requirements regarding cosmetics, Health Canada has just endorsed the use of the ISO standard 22716 on good manufacturing practices for cosmetics.

**Source:**  
[www.premiumbeautynews.com](http://www.premiumbeautynews.com)

The first step to planning your audits is to list all of the quality system processes that apply to your organization. Once your list is complete, rank the importance of each process. The best way to do this is by getting input from manufacturing, engineering, and management. A numbering scale of ten to two may be used to rank each process, where a ranking number of ten is critical and a ranking of two is slightly important. Example: In most companies, the management system process may rank as a ten, because this function is critical to the organization's quality system.

The next step is data collection. Every company should have results from previous audits and customer complaints. This type of data is priceless. Start by gathering data from the previous year's customer complaints, external audits, and internal audits. Count the number of non-conformances and corrective actions issued for that year and the process or quality system elements that they relate to. While you are analyzing the data, determine if there were any process changes. After you have determined what processes changes there were, indicate what quality system and processes were affected by the changes. The next step is to construct an Internal Quality Audit Methodology Table using the results of your data analysis (see fig. #2).

Figure #2

**Internal Quality Audit Methodology Table**

Process or Function <b>A</b>	Importance to Business <b>B</b>	Internal Audit NCRs <b>C</b>			Customer/Registrar NCRs <b>D</b>			Customer Complaints <b>E</b>			System/Process Changes During the Last Year? <b>F</b>		Total Score for Process or Element <b>G</b>	Audit Frequency/Process Change Comments <b>H</b>
		Yr	08	09	Yr	08	09	Yr	08	09	Yes	No		
<b>Process</b>		Yr	08	09	Yr	08	09	Yr	08	09	Yes	No	<b>Total</b>	
Management System	10		N/A	2		N/A			N/A		5		17	New Supplier Added
Human Resources/ Training	10						2				14	5	31	<b>Audit twice in 2010</b> New Human Resource Manager
Document Control	8			1			1				31	5	46	Process flow diagrams were revised <b>Audit twice in 2002</b>
Contract Review/ Order Entry	8			2			2				2	5	19	Use of control plans instead of standard procedures
Design & Development	8			1							2		11	
Sourcing/ Purchasing	6											X	6	
Planning/ Scheduling	6											X	6	
Packaging & Shipping	10						1				9		20	
Manufacturing Process	8			3							32		43	<b>Audit twice in 2002</b>
Infrastructure	6						2					5	13	New person in charge of Tool & Gauge Control
EHS	6												6	
Customer Satisfaction	8												8	
Corrective Action	8			2							20		30	<b>Audit twice in 2002</b>
Internal Audit	6											5	11	New Lead Internal Auditor
<b>Scale is 10 to 2</b> ↑ 10 - Critical 8 - Very Important 6 - Important 4 - Somewhat Important 2 - Slightly Important		Add the totals from columns B, C, D, E, & F for year 2009 totals					Add <b>5</b> points to the score for any system or process changes. Changes may include: New manager of system, revisions to process flow diagrams, several procedural changes, entirely new system/equipment, etc. ↑					<b>Audit Scope:</b> The internal audit team will audit the applicable elements of the ISO standard. The 4 highest scoring elements/processes on this table will be audited twice during the year. The rest of the elements will be audited once during the year.		

- Column "A" includes the business processes.
- Column "B" includes the ratings of importance for each business process. The scale describing the ratings is located under the column.
- Column "C" includes the number of internal quality audit non-conformances issued for each process.
- Column "D" includes the number of registrar/customer audit non-conformances issued for each process.
- Column "E" includes the number of customer complaints issued for each process.

## BONZA TRAINING SOLUTIONS

Po Box 21007  
Stratford, ON

Canada N5A 7V4

Toll - free: 877-508-5525

Phone: 519-508-5525

Fax: 519-508-5526

Email: [info@bonzatraining.com](mailto:info@bonzatraining.com)

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- Column "F" identifies if there were any system changes for a process during the past year. Changes such as: new employees, process changes, new equipment, new managers, etc. Add a score of five for each system change.
- Column "G" shows the calculated score for each element. The calculation is simply adding up the numbers in all of the B, C, D, E, & F columns.
- Column "H" includes comments for audit frequency and process changes.

In the example shown in Figure #2, the four highest scoring elements will be audited twice during the current year and all other elements will be audited once.

The analysis and construction of the Internal Quality Audit Methodology Table, takes into consideration the importance of your system's processes/ISO elements and where additional auditing activities should be appointed. The construction of the Internal Quality Audit Methodology Table also enables you to develop an annual audit scope and schedule that are supported by the results of your analysis. The audit scope should be included in the audit methodology table, because the table's results support and clarify the scope.

The last step is constructing an Internal Quality Audit Schedule. This step is relatively easy, since most of the schedule's framework has been determined from the results of the audit methodology. From the audit methodology results, each element or process will be audited at least once on the annual internal audit schedule. The four highest scoring elements from the Internal Quality Audit Methodology Table are scheduled twice. It is a good idea to include a span of least four to six months between each of the areas that will be audited twice a year. The schedule should be flexible, with two to three processes being audited per month. This arrangement spaces out the audits and allows for additional time to be spent on each audit. It may be a good idea not to schedule audits in December. Leaving December open allows some "wiggle" room for monthly audit adjustments during the year.

The construction of an annual Internal Quality Audit Methodology is a great tool for planning effective internal quality audits. It requires time, effort, and a little sweat. But as the old adage goes, "no pain no gain."

**References:** ANSI/ISO/ASQ Q9001-2008. American National Standard Quality Management Systems - Requirements. Milwaukee, Wisconsin: American Society for Quality, Nov. 15, 2008

**About the Author:** Mark J. Magda is a Quality Manager at Momentive Performance Materials, Inc., in Strongsville, Ohio. Mark has been employed as a Quality Manager for eight years, and has worked in various quality functions for the last twenty years. Mark has a bachelor's of science degree in automated engineering from The University of Akron, and a MBA from Baldwin Wallace College located in Berea, Ohio. Mark has been a member of the American Society for Quality since 1995, and is an ASQ certified Mechanical Inspector, Quality Technician, Quality Auditor, Quality Engineer, and Six Sigma Black Belt.

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## E-learning has opened the door to a new way of education for all ages and skill sets

By Allan Pettman

As the age-old phrase suggests, 'you learn something new every day'. But to many the word 'learning' paints a picture of a school classroom, chalk scraping over the blackboard and examination halls with tables lined up in rows. What it doesn't take into account is the social make-up and age of the working population.

But how do we accommodate all these different needs and ensure that everyone, regardless of their age and social situation, has the same opportunities? Thanks to the dawn of flexible and non classroom-based learning, there are more options than ever before. Gone are the days of structured lectures - instead we have the choice to learn in the best way that suits us.

For many learners it isn't a question of whether they want to train. It's a must. Re-training as a result of redundancy and bankruptcy can be an intimidating experience made harder by a well-established skill set. In this case, a classroom full of graduates and young employees is not always the best solution and can make the learning process more humiliating than engaging. Take engineers, for example - the nature of their job means they're very set in their ways. This makes re-education much harder, whereas a project manager who is used to flexibility generally finds it easier to pick up new ideas.

Another social influence is childcare. With expanding working hours and larger families, people aren't able to commit to regular evening slots in classrooms or in front of the computer. In this sense, collaborative learning has given people the flexibility to learn how they want to and maximise learning potential in a way that structured teaching doesn't allow.

It's important to remember that education is a very individual process that people tackle in different ways depending on their responsibilities and skill set.

A downturn always has a knock-on effect on training. It leaves staff reconsidering their roles and careers, just as organisations consider who they need and who they don't. As a result, people are more prepared to gamble with their careers. A general dissatisfaction and fear over losing their job means people are happier to retrain for a newer and more secure position.

In the case of the IT industry, a lack of skilled graduates and vacancies means there's a real need to keep training older staff in a bid to retain them and ensure the company can maintain its competitive advantage. While in theory the older and most expensive workers are cut first, in truth no company can run on graduate employees alone - the older workforce is essential for providing a backbone to any company. With the predicted skills gap and election results suggesting a cut in public spending, it has never been more important to ensure the more experienced and qualified workers hone their skills.

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Taking all of this into account, e-learning is gaining momentum and providers are becoming more savvy about engaging media and social networking, using video and Facebook rather than death by PowerPoint. While this may be more recognisable to graduates who have grown up with social media-esque inclinations, there's no doubting that this will appeal to trainees of all ages and skill sets.

Despite the obvious benefits, e-learning still needs to be managed. It's labeled as being good for theoretical learning but still needs to be blended or made collaborative with access to mentors, learning resources and hands-on development for practical skills to be cemented.

However, e-learning is without doubt evolving and has opened the door to a new way of education that benefits all ages, skill sets and backgrounds. Age is no longer an excuse for companies not to train their staff. Instead, they should be welcoming the opportunity to expand employee expertise with open arms, especially given the ease and flexibility of training today.

*Extract from U.K.'s HR Magazine - June 2010 edition : supplied courtesy of Redtray Ltd, U.K. blended learning specialists. The author Allan Pettman, is UK managing director of Global Knowledge.*

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## Featured Course: Soft Skills for Supervisors

Supervisors and project leaders are usually selected because they have great technical skills, are quick to solve problems and jump in when things get off-track. Unfortunately for them and their direct reports these are the same qualities that can get them into trouble as leader – big trouble!

For many, managing people requires a complete 360 degree shift in perspective. The job of a supervisor or leader is not to do the work (they are expert at that), but to engage and motivate others to get the job done. A whole new job, skill set and challenge!

**Who can benefit?** This course is particularly beneficial for supervisors, team and project leaders who were promoted because of their technical expertise, positive attitudes and take charge qualities.

**Objective:** During the workshop, participants will develop the understanding and skills to communicate and work with their people in whole new way. Upon completion of the workshop, they will:

1. Understand the role of a leader versus a technical expert or team member
2. Be able to step back and engage people as a way to get the job done
3. Have the skills to communicate with people in a respectful, clear and supportive manner
4. See developing people as a core strategy for achieving results

**The Process:** The workshop will be highly interactive and ask participants to apply the people and communication skills they learn to their current work situation and challenges.

### Topics covered:

- ◆ The Role of Leader versus Technical Experts/Performer
- ◆ Respectful Communication Methods and Impacts
- ◆ How to avoid Things that Frustrate and Shut People Down
- ◆ How to build Positive, Proactive Work Relations
- ◆ Facilitating Employee Involvement and Engagement
- ◆ Managing Difficult People

### Taking it back to the workplace:

At the conclusion of the program, participants will have:

- ◆ Redefined their Role as a Leader
- ◆ 5 Steps to Ensure Positive Communications
- ◆ 5 Steps to Facilitating Employee Engagement
- ◆ 8 Steps to Managing Difficult People

*This one-day workshop is available for on-site delivery, and is also scheduled to run on the following dates: (Public course fee: \$275 +HST)*

**September 29 - Guelph**

**November 17 - Stratford**

[Training Schedule & Registration Form](#)