Quality Connection

Official Newsletter of the Baltimore Section, ASQ
January - February 2005 Voice Mail: (410) 347-1453
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Message From The Chair

Sara Parker.

Happy New Year! I hope everyone had a safe and happy holiday season and spent some well-deserved time with family and good friends. I also hope that, like me, you got ALMOST exactly what you wanted for Christmas and ate lots of good food!

The Baltimore Section is committed to providing you with high quality programs and member activities. The New Year marks the kick-off of our 2005 Breakfast for Champions series. We're starting off our February meeting with a session on Quality Management at ViPS Medicare System at their site on the 10th. In March, BGE will host our Section on St. Patrick's Day, and although we won't be serving Irish coffee, we will hear about their organization's culture change process. We also have a great line-up of dinner meetings scheduled to include (date/topic):

February 15th – Employee Involvement in the New Millennium

March 15th – Health Care Speaker

April 13th – 2004 Maryland Quality Awards and US Senate Productivity Award Winners Lessons Learned/Success Stories

May 10th – Economic Case for Quality

Please keep in mind that we are always looking for interested folks to serve on our Board. If you are interested or would like to nominate someone for the Board, please contact any of the members from the contacts listing on our Section web page. Numerous positions will be open this year including Secretary, Membership Chair, etc. This is a great way to be involved and earn recertification units. Volunteering with the Baltimore Section is a fun worthwhile activity!

As always, we're looking for new ideas and suggestions to enable continuous improvements in the Section. We need your feedback and invite you to send any suggestions, comments, or whatever else you'd like to express with regard to the Section. Please feel free to contact any Board member by email or at a Section sponsored activity.

Lastly, please remember to consider receiving your meeting notices via email. The costs to print and mail the announcements have become prohibitive. Your agreement to receive email notices will allow us to keep costs low for dinner meetings and other member activities. Please ensure that you have listed your current e-mail address with ASQ and have indicated a preference to receive electronic mailings from both ASQ and the Section.

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***Message From The Chair** (Continued)*

I hope that you'll take full advantage of our Section's offerings over the coming year. Best wishes for a safe and prosperous new year to one and all!!

Newly Certified Quality Personnel

The Baltimore Section recognizes the following newly certified individuals who have passed either the October and December 2004 ASQ exams.

Certified Quality Manager

Stephen Kappesser	Tyco Electronics
Ajay Basavarajaiah	

Certified Reliability Engineer

Grant Schmeider

Certified Six Sigma Black Belt

David Calvert	Calvert Consulting
Jeffrey Steward	JLG Industries

Certified Quality Auditor

Kay Duchesne	Northrop Grumman
Kimberley MacLean	Becton Dickinson
Meg Bruno	Computer Sciences
Lisa Lam	Arinc
Ruth Vassey	Quest International Flavors
Kathlyn Connolly	COLA
William Gebele	Quest International Flavors

Certified Quality Engineer

Nirav Shah	
Jeremy Reitman	Rock Tenn
Robert Frank	Becton Dickinson

Certified Quality Improvement Associate

Julia Theodore	IRS

Certified Software Quality Engineer

Carolyn Fisher	VIPS

We commend each of these individuals that have successfully achieved these Certifications. They have reached a new level in their professional growth.

Section Pass Rates - October, December 2004

Exam	Total	Pass	Per Cent
CQA	8	7	87.5%
Qual. Mgr.	4	2	50.0%
CQT	4	0	0.0%
CRE	1	1	100.0%
SSBB	2	2	100.0%
Cal. Tech.	1	0	0.0%
CQE	5	3	60.0%
CQIA	1	1	100.0%
CSQE	2	1	50.0%

Comments on Certification

Kay Duchesne, CQA - I don't think the test is as difficult as the class. However, I would recommend that the prep class be taken. There is a lot of information in the prep material that is not necessarily germane to a specific job, but is more general to the field of auditing. If you don't take the class, you have to ferret out the important stuff for yourself. Not an easy job considering the amount of information involved.

Rob Frank, CQE - As the Engineering Manager for the Rapid Manual Testing plant (we make rapid Flu tests, Strep tests, etc) I am not in the Quality Department but rather Engineering. However, working within an FDA regulated industry in an ISO registered company, quality systems are a major focus, to say the least. I had completed my Six Sigma Black Belt certification a couple of years ago (an internal BD program developed with and sanctioned by the Juran Institute) and felt the QE certification would be a natural extension of this training and appropriate for my career. I self trained, primarily from Benbow's "*The Certified Quality Engineer Handbook*", Breyfogle's "*Implementing Six Sigma*", and using the various practice tests available. As I dug into the quality systems related material, I realized that what I did daily at work had already exposed me to a great deal of this material. I found the test itself challenging, and utilized the entire 5 hours. I was unsure of the outcome, partially because I had not seen any guidance on what performance was necessary to pass. I was happy to learn I passed.

Stephen Kappesser, Quality Manager - My preparation for the CQMgr exam included 2 years of hands-on work-place experience as a National Quality Manager facilitating ISO 9001:2000 and ISO/IEC 17025:1999 certifications for Davis Inotek Instrument's (based in Baltimore) several commercial calibration labs scattered around the US.

I also devoted many, many hours of self-study using a CQM Primer and practice exams. Unfortunately I failed the exam the first time I sat for it last March - I just missed hitting the passing grade by 20 points.

I sat for the exam again in October after 6 more months of aggressive work-place experience and a moderate amount of self-study, and passed it this 2nd time.

Meg Bruno, CQA - I enjoyed the certification process. I studied using ASQ's e-Learning course for Quality Auditors as well as reading various texts. Although the exam was challenging I had about 30

minutes at the end to review answers. I felt fairly comfortable with the result. Overall, the experience has been positive.

Kim MacLean, CQA - I am very happy to have passed the CQA exam. I took the ASQ prep course taught at CCBC by Lloyd Dixon and others and that was very helpful in my success. Having to go to the class helped me to focus on studying the required material. I think that had I done independent study, I would have procrastinated and maybe not been adequately prepared. Lloyd and the other instructors were very helpful in offering personal experience to go along with the training material.

Certification

Certification is formal recognition by ASQ that an individual has demonstrated proficiency within and a comprehension of a specified body of knowledge at a point in time. It is peer recognition and not registration or licensure. Since 1968, when the first ASQ certification exam was given, more than 85,000 individuals have become certified through ASQ, including many who have attained more than one designation. Although ASQ membership is not a prerequisite for certification, most of the people who hold one of these designations do belong to the Society. Certification ranks as one of the top benefits of ASQ membership.

ASQ certification is awarded to candidates who meet three criteria:

- Have a specified level of education and/or experience
- Provide proof of professionalism
- Pass a standardized examination in the certification area. (Exams are given in the English language only.)

In today's world, where quality competition is a fact of life and the need for a work force proficient in the principles and practices of quality control is a central concern of many companies, certification is a mark of excellence. It demonstrates that the certified individual has the knowledge to ensure the quality of products and services. Certification is an investment in your career and in the future of your employer.

Certifications offered by ASQ:

- **Calibration Technician (CCT)**
- **HACCP Auditor (CHA)**
- **Mechanical Inspector (CMI)**
- **Quality Auditor (CQA)**
- **Quality Auditor - Biomedical (CQA - Biomedical)**
- **Quality Engineer (CQE)**
- **Quality Improvement Associate (CQIA)**
- **Quality Manager**
- **Quality Technician (CQT)**
- **Reliability Engineer (CRE)**
- **Six Sigma Black Belt (SSBB)**
- **Software Quality Engineer (CSQE)**

ASQ Certification Rates Going Up

On January 1, 2005, the following new certification exam fees went into effect:

Certified Six Sigma Black Belt

ASQ Member Fee	$180
Non-Member Fee	$330
Retake Fee	$130

CHA, CQA, CQE, CRE, CSQE, CQA-Biomedical

ASQ Member Fee	$210
Non-Member Fee	$360
Retake Fee	$160

Certified Quality Manager

ASQ Member Fee	$270
Non-Member Fee	$420
Retake Fee	$220

CQT, CMI, CQIA, CCT

ASQ Member Fee	$155
Non-Member Fee	$305
Retake Fee	$105

Recertification

For those that were due to recertify by December 31, 2004 and have not submitted their recertification packages, you are reminded that to maintain the certification, you must submit your information to **Joel Glazer**, Recertification Chair, by June 30, 2005. This 6 month grace period is intended to give you time to gather all of the necessary documentation. You should already have accumulated the 18 Recertification Units by your certificate's expiration date. All information should be sent to:

Joel Glazer
2021 Jolly Rd.
Baltimore MD. 21209-1013
Telephone: 410.765.4567 (Work)

Incoming ASQ President's Remarks

Inaugural Remarks of Daniel M. Duhan, Incoming President of ASQ - as prepared for presentation at the ASQ Annual Banquet, Toronto, Ontario - May 25, 2004

Thanks Ken. I am very grateful for the unwavering support that you and Liz have given me, as well as the support of the entire Board of Directors, staff, Past Presidents, and of course my family.

Good evening everyone. It's so nice to see so many friendly faces. Everyone enjoying themselves? Good food? Great company? My sense, however, is that you are here for something more than the food and the ambience.

You are here this evening because you care about Quality. You care about ASQ. You are interested in our challenges, our successes, and our future. You want to learn more about ASQ's emerging role within the global community of Quality. And how together our society, our profession, and the quality movement will continue to realize our full potential.

Quality is like water. It's essential for life—a key ingredient in almost everything we do. No matter how it is applied, whether in its pure form or as part of a complex recipe, it never loses its basic properties. It's a catalyst for change. It's everywhere—and used by everyone to various degrees. Sometimes purchased, sometimes free. Sought after—even coveted. Easy to take for granted, but impossible to live without.

Our quality journey is like a large body of water.

Picture a pristine pond on a nice spring day. Perfectly calm on the surface but teeming with life just below. Quality in its pure form.

Now imagine a rock being dropped into the middle of the pond. The rock breaks the surface, and from this starting point waves radiate out across the water.

In the beginning ASQC was a small dedicated group of technical professionals, focused on products and manufacturing.

But the waves in the pond are not static. They continue to expand over time.

Like the expanding waves, ASQ and the quality profession expanded. Into products and services; into management systems; interacting with other stakeholders such as education, government systems, and healthcare. Quality has moved upstream from inspection sampling to corporate boardrooms.

If we continue this metaphor, the waves in the pond will continue to expand until they eventually reach the boundaries of the pond. But this is not the end . . . . this is just the beginning. The waves will begin to reflect back onto themselves, interacting with other waves, within different layers inside the pond.

Like the pond, Quality does not exist in a vacuum. We are bound by social and economic constraints, market pressures, customer demands, and the inevitable challenge to adapt and evolve.

Quality is no longer the exclusive domain of a small group of professionals.

While we will always serve the technical experts who are the stewards of the quality profession, and continue to contribute to the expansion of our knowledge, more and more our destiny lies in serving the larger constituency of individuals who care deeply about quality. Individuals who do not have the word quality in their job title or as their primary job function. They are the quality advocates, and increasingly they are our future.

When you stop and think about it, isn't everyone a quality advocate? When you buy a new toaster or get your haircut you care about the quality of the products and services you receive.

Does anyone wake up in the morning and say it's OK to buy a refrigerator that only works sometimes? Or, it is OK for the local pharmacist to give you the wrong prescription sometimes?

Like the pond, our quality journey has sometimes been calm; sometimes turbulent. But always exciting.

Today ASQ is facing declining membership and struggling, in a fast-paced world, to find and support volunteers. The governance model that has served us since our inception may not be the best model to carry us into the future. But challenge and change are not new to ASQ. Throughout the history of our Society we have faced many challenges.

I remember as a Section chair in the '80s the debates over governance and international activities. How we celebrated when we finally reached 50,000 members. I remember as a Division leader in the '90s the name change from ASQC to ASQ, the constitutional convention, and the establishment of ASQ's "Washington presence." And I remember in the '70s concerns regarding financial viability.

I remember my father discussing whether we should move the Society out of Milwaukee. How my uncle debated the Society's governance and the role of headquarters vs. the role of the local member units.

In every situation, the leaders of our Society met the challenge, developed and implemented innovative solutions, and grew collectively from the experience. We did not abandon our roots. Rather, we created new opportunities while honoring our traditions.

Yes, I have been a member for only 25 years but I have been associated with ASQ almost all my life. Some families have generations of doctors, some lawyers, some police and some fire fighters. My family has generations of quality professionals. And while I have not had quality in my job title or job description for over 10 years you can never take quality out of the individual.

Our Society is a very special place. We have changed how people think about products and services; how companies and governments are managed; and how we view the role of personal accountability.

Our members have changed the world, but we seldom if ever acknowledge, much less celebrate, our contributions. Our nature is to work quietly, and to work hard.

But this is not the ASQ or ASQC of the '70s, the '80s or even the '90s. Not the ASQ of my father's, uncle's or cousins' generations.

Today there are more opportunities than ever before to discuss concerns, share new ideas, and engage people and organizations. ASQ and its members are embracing these opportunities—with gusto!

Several of our members are highlighted in the booklet that you found at your seat this evening. And in the video that you saw Monday morning.

The booklet and the video are just two components of a major awareness campaign being introduced throughout 2004 in which ASQ celebrates who we are. The campaign, which targets both existing ASQ members and the general public, is meant to enhance the image of the quality profession and to generate increased awareness of ASQ.

These faces represent the great vitality of ASQ and the quality movement today. They are the faces of youth—spirited, ready to take on the world, eager to try new things. Which is fitting for ASQ, as we continually take on new initiatives.

Our Living Community Model opens the door to many more of these young faces by providing them with an unprecedented level of options for becoming an ASQ member. The Community Good Works program is putting into action our firm belief that quality is universal and as such can be a catalyst for improving our local communities.

These are the faces of experience—wise, knowledgeable, and steady. We rely on this level of experience as a guiding force behind everything we do.

For example, ASQ is completing year two of our Living Strategy approach, which taps into our enormous pool of knowledge and wisdom by continuously engaging members, customers, and quality advocates at multiple levels. With the Living Strategy approach, we are evolving into a vibrant organization that can rapidly and objectivity take advantage of emerging opportunities while still maintaining our core focus. Gone is the notion that strategic planning is a fixed event done once a year by a small select group of individuals.

And there are other examples. We have begun work on an ambitious and exciting plan to put quality back on the corporate executive agenda by establishing the economic case for quality. We are becoming more proactive—offering the wisdom of quality and the knowledge of ASQ to policy makers and the media.

And, yes, these are the faces of diversity, reflecting the richness of talent and ideas and backgrounds that share a place within ASQ.

These are the faces of quality.

These are just some of the many things we do as ASQ that touch everyone's lives, every day, 24 hours a day, 365 days a year, making a difference one person at a time. I am always amazed and extremely proud of all the neat things ASQ is doing around the world.

Today the role of the quality advocate is not limited to industry. Our members are making a difference in our local communities and on a national level.

ASQ must continue to embrace individuals—like me and so many others—who don't have quality in their job titles but who care passionately about quality. After all, who buys a toaster that only works sometimes?

Each day we are embracing more and more non-traditional stakeholders as we continue to live our vision that quality is essential; quality is universal; quality has limitless potential. And that, ultimately, ASQ's mission is to improve the quality of life for everyone throughout the world.

Earlier this evening I used a water metaphor to talk about quality. How even though water is hard to live without, it's very easy to take for granted. That's the perfect metaphor for what I believe is the central dilemma facing ASQ and the quality profession today.

In spite of what we have to offer, we have a perception problem—a recognition problem. Quality

often is seen as a highly abstract concept. When in fact it's as real as flesh and blood.

Quality has a personality. It has a face—multiple faces. 100,000 faces we call members and a million faces that comprise the quality community. Quality is us—each of us, and we all have a story to tell.

One of my priorities as president will be to make sure we get out and tell these stories. Why? Let me share with you two examples.

At the member level, consider individuals who are either between jobs or looking to advance in their current occupation.

When I mention McDonalds, Harvard or Boeing you can instantly recognize who these institutions are and the potential value someone from these organizations could bring to your company.

Advocating ASQ leadership experience or ASQ certifications may have no impact if the employer or potential employer has no idea who ASQ is, what it does, or why someone who is associated with ASQ can have a positive influence on the bottom line. Conversely, an association with ASQ, when presented to an informed organization or individual, could be the one characteristic that distinguishes you from the rest of the pack and allow you and your organization to move ahead when everyone else is standing still.

At an institutional level, consider ASQ's experience with the Chimes, a $130 million dollar international not-for-profit organization dedicated to helping people with disabilities.

Two years ago no one at Chimes knew about ASQ. Today members of Chimes attend ASQ events and ASQ is sought out on topics like metrics and process improvement. Through relationships like Chimes we are demonstrating the economic case for quality. How, utilizing the tools and systems we use every day as Quality professionals, we can improve local communities and create a body of evidence that documents the impact of quality.

These are not isolated examples. These experiences have been repeated over and over again with organizations like the National Geographic Society and the city of Kingsport, Tennessee, and individuals across North America.

Once ASQ is "discovered" it becomes a prized possession, coveted and cherished for both its strategic and tactical importance. So we must take bold steps to enhance the image of ASQ and the image of the quality profession.

I want the name ASQ to open doors for our association collectively and for each one of us individually.

ASQ gets under your skin, and it doesn't come out.

You are the face of quality. I ask you to join with me—with your American Society for Quality—as together our society, our profession, and the quality movement realize our full potential.

Enjoy the rest of the evening. Thank you, and good night.

Minimizing Product Liability Litigation

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Summary

This paper addresses the excessive amount of lawsuits in the United States and the reason individuals or organizations are sued. It explains why organizations become vulnerable and the consequences of their exposure to litigation action.

The paper emphasizes the near future trend of product liability both in the United States and globally and suggests what manufacturers can do to minimize product liability litigation. It promotes the need for organizations to make changes to their existing methods of addressing product liability prevention and product safety initiatives.

Finally, it suggests why a company should have a formal product design review comprised of a multi-functional team representing various disciplines in the organization. This activity should be divided into four stages: The *Inception Stage, Preliminary Design Stage, Release Stage, and* Post *Production Stage.* All four stages are explained in detail with recommendations of incorporating each stage into the organizational system.

This year alone three of my personal friends, a neurologist, a cardiologist, and a general practitioner, all decided to close their practices and retire due to the high cost of malpractice insurance. Each of these medical doctors were frustrated and stressed because of the potential exposure of being sued and the high cost of financial protection.

Interestingly, none of these physicians had previously been sued - but that does not really matter! The problem of potential lawsuits and the high cost of

liability insurance have forced many organizations to rethink their position of staying in business. Or, if they are a manufacturer simply take a risk of operating without product liability insurance. Most recently, a customer sued an owner of a rental store and won a verdict because the customer was injured when the snow blower he rented damaged his leg from gravel that flew from the blade of the blower while clearing snow from his driveway. The rental store did not have product liability insurance and subsequently was forced to close their doors.

Today we live in a time where civil lawsuits flourish and people are sued for any reason - no matter how frivolous or nonsensical it may seem! If your leaves blow into a neighbor's lawn or if a cup of coffee is to hot at a fast food restaurant, you or that restaurant owner can be sued. There is case after case of what might seem to be unfounded litigations that has resulted in the plaintiff receiving financial rewards from their total neglect or misuse of a product.

Even if a defendant should win a foolish or unfounded lawsuit there are still the legal fees that are involved in the defense process, not to mention the time and stress of the participants, as well as the negative publicity oftentimes associated with a lawsuit. If the organization is a manufacturer of a product the company may become even more vulnerable. The plaintiff may perceive the company as a high potential for greater financial reward - the so-called deep pocket scenario comes into play. It is estimated that product liability costs the government, manufacturers, and insurance companies well over $100 billion annually. (Goodden, Randall, 2000, Product *Liability Prevention . A Strategic Guide*. Quality Press)

Similar to the above mentioned medical practitioners many small manufacturers have decided to go out of business rather than take the chance of a lawsuit and expose themselves, and their family, to the stress of potential litigation and possible bad press. Many other small manufacturers have elected to produce products without paying liability protection insurance, taking a chance that they will not be sued.

Some of the larger companies that employ thousands of people have been negatively impacted economically because of lawsuits. For example, Owens Corning's asbestos issues and Philips. Aztec Division chemical explosion resulted in litigation action against each company.

Ostensibly, this litigious virus does not show signs of lessening. In fact, in the last few years it has accelerated in the United States and has spread to virtually every corner of the world due in part to global competition. Although reform bills have tried to control the litigation explosion, the litigation process will continue to be fueled by two main factors. First, the desire of the individual to seek monetary compensation, or in other words the get rich quick desire; and secondly, the desire of the legal profession, who stands to share in the deep pocket opportunity, and whose financial interests represent both the plaintiff and the defendant. The strength of these two factors will continue to put pressure on any future reformation of minimizing the litigation process.

Can we minimize product liability litigation? The answer is *yes*! But like any problem we must first realize that we have a problem. The messenger presenting top management the possibility of product liability exposure is not a comfortable position. Essentially, that person is saying to executive management that the organization must recognize a potential problem and take the necessary action to prevent the occurrence of a product liability situation.

This action is usually translated into making changes to existing methods and / or processes. These changes could include adding additional processes or manpower and increasing operating cost. None of these actions are popular initiatives with management. In fact, they are usually extremely unpopular because they send a message to management to add cost, which is an adverse proponent of most company's business goals - which is to cut cost. In a global economy where business is highly competitive and the drive is to reduce cost product liability becomes an undesirable activity.

If a company has not had a previous liability action and has not made a commitment to a preventive action then why would they want to commit to such an endeavor? They would simply argue that the money spent on product liability prevention could better be spent on improving productivity or a better returns on investment. Essentially, they feel that the drive for survival is reducing cost and working more efficiently; and metaphorically speaking they contend, that if the company is not sick why have health insurance? However, the answer is equally simple. Liability action can happen for any reason - be it foreseeable or unforeseeable, misuse or abuse, justifiable or an unjustifiable application of the product. If a liability action happens the organization may not survive.

Product liability prevention activities do not have to be excessively costly to an organization. If done in a structured and planned manner and by applying a few simple methodologies and incorporating them into our

existing operating system. The first step in a product liability prevention process is the product safety initiative. This step starts with the formation of a Design Review Team. The Design Review is a technical evaluation of the production processes, components of the product, and finally the product itself. The Design Review should include product safety and hazards analysis. The Design Review Team should be comprised of representatives from design engineering, reliability engineering, quality engineering, application engineering, manufacturing engineering, production operations and sales engineering. In larger organizations each of these disciplines would stand alone with the in-depth knowledge and skills to contribute to the various product safety parameters. However, in small to medium size companies some of these disciplines may be combined into one department or even one person's task.

The Design Review should begin at the *Inception* stage. This stage is the embryonic stage where fact gathering and determination of customers needs are identified. Once this information has been obtained and recommendations of how the product should be developed and to specific characteristics it is followed by the *Preliminary Design* stage. This stage should address the process capability including quality compliance, material durability, reliability, needed instructions and other criteria that could cause a potentially unsafe product. Once the feasibility functions have been evaluated the next stage is the *Release* stage. This is the pre-production approval process, which would address any problematical situation that was not identified at the prior Design Review stages and resolve those issues. The last stage is the *Post Production* state. The initial Design Review Team members would conduct a review to assess any failures or potential failures in productivity, usability, serviceability, or reliability of the product. All four stages should address the possible misuse or abuse of the application of the product and the foreseeable and unforeseeable environmental and safety issues that may arise.

The *Inception* stage would focus on the safety aspects as one of its concerns. This assessment would begin at the time the organization has determined the need for a new product or a potential need for modification to an existing product. At this point when a need exists that can show value to an existing or a potential customer, the Team should use think tank tools (such as brainstorming, mind mapping, cause and effect matrix, tree diagramming, etc) to determine potential problem and safety issues. This pre-formal stage of the product development processes is oftentimes referred to as The Fuzzy Front End and is a virgin territory for enormous opportunities. This is the stage where the Design Review Team decides the initial feasibility of a new or revised product. It is also the time to appraise possible market conditions and apply the latest technologies in the industry and use best practice concepts.

At the point a Design Review Team has been formed for a particular project the Team members should elect a Team Leader and a Team Recorder. The Team should follow an exploration process and these activities should be recorded in a Design Journal. This Design Journal would be used to log the Inception Matrix which would take large amounts of data and concept ideas and reduce them to a salient single opportunity initiative or problem solution.

The Inception Matrix would assign a name to the potential opportunity/problem, a classification of idea focus, a mode of idea dissemination, and the benefits of the idea. For example, lets suppose your organization is a producer of pastas, and for years your product has been extremely popular in the marketplace and sold around the world in many varieties and types of pasta. But today's consumers desire for cholesterol free and calorie reduction has subsequently caused a decline in pasta products and consequently resulted in a decrease in your sales by over twenty-five percent.

This significant revenue reduction has forced you to construct a new product that will combat this downward trend in sales.

Inception Matrix

Name	Idea Focus	Idea Mode	Idea Benefit
Healthy pasta	People want to eat healthy	Provide a pasta low in calories and cholesterol	Satisfy customer Increase sales & revenue

Table 1

Following the Inception Matrix a name would be assigned after a name review exercise.

The *Inception* stage will address essentially all aspects of the justification or reason to continue or discontinue with the development of the new or revised product. Product safety and liability prevention must be introduced at this embryonic level. In the case of the revised pasta product we must be concerned not to harm the consumer with additives or ingredients that could create other health impaired conditions. In essence, solving one problem but creating another! At this stage a Process Plan should be developed to include a detailed evaluation of product safety and the application of the product or the possibility of misuse or abuse of the product by the consumer.

The *Inception* stage should be driven by the business goals. For example, the organization's strategies could be to increase productivity, reducing total quality cost, simplifying manufacturing processes, or obtaining advantage over the competition. The opportunity identification process most likely precedes idea generation or product enrichment, and it may occur from an individual or a team initiative and focus on all or part of the business goals (such as unmet customer needs, inefficiency in production, or excessive internal scrap).

The *Inception* stage is essentially the first line of attacking the condition that may cause situations for an unsafe product to enter the marketplace. This is the time to devote ample resources of manpower and sufficient time allocation to prevent problematical issues later in the process and to minimize the possibility of potential product liability litigation.

After the Design Review Team has completed the *Inception* stage of identifying and recommending how the product should be developed to specific characteristics and safety precautions parameters, the Team will now be ready to move to the *Preliminary Design* stage. This stage should address the process capabilities, the machine capabilities, the quality compliance requirements and other quality issues, material durability, reliability criteria of product applications, needed procedures and work instructions, product safety instruction (where applicable), and any other issues that could cause for an unsafe product.

This collaborative process is a critical step in the product safety and liability prevention initiatives. This stage is characterized by high uncertainty regarding the product and the processes used to manufacture the product. This precursor to production is basically where the forces of expediting the final design to start production and to quickly get the product in the marketplace is at its highest. The pressure by sales, and oftentimes production, to release the design early may force the preliminary design team to neglect product safety inputs that could result in an unsafe product released to the marketplace.

The caveat safeguard from having this time constraints from occurring is for executive management to provide ample time to perform this function. One effective method is to have the Product Design Review Team develop an agenda of items to review, including Risk Identification, Risk Analysis and Risk Response initiatives, and submit this with tentative timelines for each agenda item along with subsequent progress reports to top management.

Each of the agenda items should use the attributes of cross-functional contributions to review the preliminary design drawings and specifications prior to production release. The Team should be versed in product design evaluation techniques and safety tools. These tools and techniques may include both statistical and non-statistical application methods such as failure-modes-and-effects analysis, fault-tree analysis, triggers, assumptions analysis, human-factors analysis, and checklists. These tools should be used to support concerns and assumptions of the Team and the product.

These techniques and tools should also be used to assess the risk of a nonconforming product entering the marketplace in relationship to the safety magnitude of the non-conformance, and the potential liability of early product failure in the hands of the user of the product. They also can be used to disseminate between risks and issues. For example, a risk may be a malfunctioning windshield wiper whereas an issue may be a defective car compact disc. The windshield malfunction could cause an accident that consequently could cause loss of life or peril to the driver or passengers of the vehicle. However, the defective compact disc, although a failure will not cause loss of life or peril to the driver or passengers but only a discomfort or inconvenience to the people in the car.

Try to make the concerns in the *Preliminary Design* review as specific as possible so as to better delineate between what are issues and what are risk. Once the risk of a potentially unsafe product and the potential product liability have been identified these should be prioritized and intergraded into the design parameters. This *Preliminary Design* review would also allow all departments involved in the

manufacturing process to critique the proposed product design and input their concerns for a safe and reliable product.

The *Preliminary Design* review would also allow these departments to review proposed drawings and/or specifications to ensure the organization has the capabilities to build the product to the design criteria. If not, make the necessary changes to the processes, materials, or design to satisfy the concerns of the pre-production initiatives.

The third opportunity for the organization to minimize product liability litigation is in the pre-production approval process timeframe called the *Release* stage. This stage is a review of the product design held after the drawings and/or specifications have been released to production and the initial production samples have been produced. This is the appropriate period to examine the product before it becomes economically more costly in commitment time and before a potential production or field problem may occur.

This *Release* stage is critical to the successful launch of a new or revised product because it is a pivotal point between the product design review's initial output and the early stage of production. Considerable pressure is sometimes introduced by the sales and marketing group and by operational management upon the production department to ship products to the marketplace before the competition. Yet it could be a costly mistake to shortchange environmental testing, lifecycle testing, durability testing, and reliability testing, or configuration appraisal.

Every effort should be given to conduct reliability and durability testing both in environmental simulations and actual live testing in the field. Most of this testing will be conducted by the New Product Development group, the Reliability Laboratory, or even an outside third party testing lab, and forwarding the formal report and testing data to the Product Design Review Team for their review and decision making actions. The Team is an integral part of the *Release* stage (Pre-production initiative) and the decision gate for any action that needs to be taken.

In this *Release* stage the Team is less active than in the *Inception* and Preliminary *Design* stages, but have ownership of the new or revised product design and should uniformly decide whether or not to release the design to production without any further appraisal activities or constraint issues. If additional testing, analysis, or resource actions are required by the Product Design Review Team they must communicate this activity and the timeframe to complete the activity to top management and all affected operational departments immediately.

Today's organizations are subject to immediate and dynamic changes not only in the way the product is manufactured, but also in the task being performed. With the current initiatives such as Lean Manufacturing, Reengineering, and Six Sigma many organizations have elected to modify task, which oftentimes, results in downsizing of personnel. In this situation it is not uncommon for information to be misfiled or completely lost. Therefore, documents may be the only proof the company has to ensure the design of the product with safety concerns has been addressed. These performance documents such as Guideline documents, Specification Content and Format Guideline manuals, Design-Standards documents, Workmanship Standards documents, Safety Code manuals, Change Control Procedure document, Engineering Test Procedure documents, Warning documents, Checklist and Inspection Procedure documents, and Public Relations Procedure documents must be subject for review at the *Release* stage by the Product Design Review Team to assure product safety issues have been properly documented and a product liability prevention initiative has been intergraded into the operational system.

The last stage of the Product Design Review activities is the *Post Production* stage. The same Team members of the previous three stages are active in this stage. However, this stage is a review to assess any failures or potential failures in producibility, usability, serviceability, durability, or reliability of the product in the real-life environment.

This stage would encourage the Product Design Review Team to use the quality cost data for both internal and external failure cost as a baseline for determining the product performance factors. These quality cost factors coupled with other data such as productivity, machine and equipment downtime due to material or tooling problems, and additional application testing would serve the Team for any needed product design action.

The *Post Production* activities may also include investigation into the organizations past and present liability exposure and any litigations against their competitors. The *Post-Production* review should meet at least quarterly for three years after the *Release* stage to validate the product design process effectiveness. They should take appropriate action, when necessary,

to resolve any product safety and product liability prevention issues that may arise.

It is also recommended to conduct post-testing of any characteristic or concern to verify that no changes have been made in the process that may adversely affect the product. The Design Review Team should also be cognitive to any outside changes in the application of the product that might cause an adverse condition and respond immediately to resolve.

Clearly, these four stages of the product design review process can be time consuming and take away from other assignments of the Team members. However, if anyone of these stages can minimize the possibility of a product liability litigation action or, more importantly, minimize or eliminate the possibility of an injury or loss of life due to an unsafe product then these activities are well worth the cost and the time of the Team members and the organization.

Sam Berlin

The Section has learned of the recent passing of **Sam Berlin**, an active member of the Baltimore Section from the mid-1950's through the mid-1980's. He was the Quality Manager for Maryland Cup in downtown Baltimore. He served the Section in various positions, both on the Board and as an instructor of quality-related courses sponsored by the Section. During the 1972-73 Section year, Sam served as the Section Chair. Our condolences are extended to Sam's family.

Section Mailings

The Section is now making use of e-mails to provide notice to the members of upcoming meetings, both the dinner and breakfast meetings. If you have previously allowed ASQ to send you information electronically, you will be receiving your notices via e-mail. However, you must make sure that ASQ has your current e-mail address. You may contact ASQ at help@asq.org or at 1-800-248-1946. You may also update your information on line at www.asq.org by entering your membership number with your first name as the password. You will then be requested to change your password. If you have said "No" to receiving any electronic communication for ASQ and the Section, you might want to reconsider this. For each member that allows the receipt of Section e-mail, the Section is able to save $10 in printing and distribution costs. An added benefit is timely delivery of information, which might not have occurred using bulk mail non-profit permits.

Grace Hosts Chinese Executives

By Eric Whichard

In January a diverse group of executives and professionals from Shanghai (China) industry, government, and military was hosted by W.R. Grace & Co. at its headquarters in Columbia, MD.

Their trip was organized by the Shanghai Association for Quality (the SAQ, chartered in 1982), and executed through the University of Baltimore's China Program for the purpose of learning about how US businesses are using Six Sigma.

The SAQ is separate from, but in some ways similar to, the China Association for Quality -- which is in some ways similar to our own ASQ. The China Association and the American Association work together in certain respects, as I understand it. I was not even aware that these organizations existed in China.

In this area, in addition to Grace, this group visited Dupont, Northrop Grumman, and Bechtel. They are now traveling to other regions (e.g. New York / New Jersey, Chicago, Houston, the West Coast) to visit other firms.

They spoke very little English, and arrived with an interpreter. Several of our local Mandarin speaking employees participated. They contributed greatly to the sense of welcome, and helped further bridge the language barrier.

In addition to providing a learning opportunity, we hoped to develop more contacts with which to do business in China.

One of our officers commented that in 1987 Grace became the first wholly foreign-owned company to be licensed to do business in The People's Republic of China with its can sealing plant in Shanghai. Several of our visitors recognized the name and knew of our operations there.

A Grace officer presented an overview of the company and what it has accomplished using Six Sigma. I presented an overview of Six Sigma at Grace focusing on key success factors. Making a presentation through an interpreter was a whole new experience for me. But I seem to have survived.

Science Fair Judges Sought

March 2005 is the 50th anniversary of the founding of the Baltimore Science Fair and special recognition events are planned. The Section is seeking judges to again participate in judging Science Fair projects at the regional level for the use of statistical methods and for teamwork. If you are interested in judging for the Section, please contact **Kevin Gilson** (410-884-9165 or kgilson@earthlink.net). The dates of the event in March will be announced soon and you will be contacted to determine your availability. If your organization would like to provide recognition pieces, such as copies of the Memory Jogger II or similar materials used in your TQM programs, please contact Kevin.

ASQ - Baltimore Section 0502

THE VISION: ***To be the Baltimore Metropolitan Area recognized resource on issues related to Quality.***

OUR MISSION: ***To create value for our members and others by providing opportunities for development and resources for managing quality in the community.***

Certification Exam Schedule

Examination	Application Date	Exam Date
CQE/CQA/ CSQE/CQIA/ CCT	April 01, 2005	June 04, 2005
CQT/CRE/CMI/ SSBB/HACCP/ Biomedical/ Quality Mgr.	August 19, 2005	October 22, 2005
CQE/CQA/ CSQE/CQIA/ CCT	October 07, 2005	December 03, 2005

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