Chairman's Message
When Quality Systems Fail …
To Do Their Job

Frank Vojik

By now everyone is familiar with the Bridgestone/Firestone tire failure responsible for over 100 deaths and several hundred injuries nationwide. Internal investigations have led some to conclude that the company's QS-9000 management system had a part to play in this incident.

Testifying before congressional subcommittee members that are investigating the production of tires allegedly linked to these deaths and injuries, a key quality executive of tire manufacturer Bridgestone/Firestone blamed QS-9000 at least in part for the failure leading to the recall of 6.5 million tires.

In a recent issue of Quality Systems Update, it was reported that Robert Wyant, vice president of quality assurance for Bridgestone/Firestone told the subcommittee holding hearings on the situation that "Maybe QS-9000 is a causal factor here. QS-9000 encompasses the entire plant from front to back and that's my comment."

What the article did not include and could not address was the possibility of litigation affecting Bridgestone or the registrar. And we all know that's on the horizon - and rightfully so.

For quality professionals such as us, this is most unwelcome news. We talk about "doing it right the first time" and "mistake-proofing," and "consistently meeting customer requirements." We serve as the standard bearers for quality and act as quality improvement advocates both inside and outside our organizations. It's distressing when we read anything negative related to quality - even more so when people's lives and safety are at stake.

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Chairman's Message (Continued from page 1)

Nevertheless, this situation can serve as a reminder for many of us that those quality management systems -whether QS-9000, ISO 9001, or ISO 14001 are just that - management systems, not guaranties of product quality. It's for very good reasons that registrars prohibit the use of their watermarks and legends on products!

However, the quality system should have processes in place to bring defect data and customer feedback to the attention of management representatives and quality analysts. The quality system should have mechanisms in place to bring these complaints to executive management review. The system should have an effective corrective action process in which complaints are received, analyzed, investigated, and corrected. The system should provide for the implementation of effective preventive action to prevent recurrence.

**The operative word is effectiveness.**

The task that many of us who manage quality systems now have is to reevaluate the effectiveness of our management systems, to determine just how well we deliver a consistent product, defect free, with prompt and effective remedies in response to internal and external customer complaints. The legal system is now looking at it very closely. Our registrars should already be requiring it, and our customers are demanding it.

My question for you is - Just how effective is your quality management system?

Hazard Analysis Critical Control Point (HACCP) by Lisa Brown

ASQ has responded to the current interest in the Hazard Analysis Critical Control Point (HACCP) concept by offering the new CQA-HACCP certification. The new certification is intended as an add-on for those members already holding the CQA certification, but would like to gain recognition for their knowledge of the HACCP principles.

The CQA-HACCP certification is certainly destined to become a preferred credential for the quality or regulatory professionals working in industries regulated by the FDA, particularly those associated with food, biomedical products, or medical devices. The government is looking to utilize the HACCP plan as the basis for performing abbreviated inspections in the future. Through this approach, FDA will continue to protect the health and safety of U.S. consumers by focusing on the areas in a product or its manufacturing/distribution processes that would contribute to a hazardous situation if a regulated facility were not operating under the appropriate controls. The advantage of this inspectional technique to the industries regulated by the FDA is inspections of shorter duration with a very specific scope. While, the government and consumers find the approach appealing because it will allow for the inspection of more facilities without adding additional tax burden. By shortening the inspections to focus only on control points related to hazards, everyone wins.

This presentation will briefly introduce the seven principles of HACCP based on the Body of Knowledge for ASQ’s CQA-HACCP certification exam.

The Seven Principles are:
1. Conduct Hazard Analysis
2. Determine the Critical Control Points (CCPs)
3. Establish the Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Verification Procedures
7. Establish Record-keeping and Documentation Procedures

**Principle 1: Conduct a Hazard Analysis.**
**Identify Hazards** -- To begin a hazard analysis, you must first identify the characteristics of the product that could result in a hazard to the user (and/or the patient in the case of a medical device). This analysis should include potential failures, in addition to those known to have occurred in the past with similar products. Consideration is to be given to hazards that could result from faulty or misuse of the product, as well as normal use.

**Evaluate Hazards** -- Once the hazards are identified, the list is evaluated based on the severity and likelihood of occurrence. Those hazards that are not regarded as severe based on the seriousness of the consequences resulting from an exposure to a hazard, or those that are unlikely to occur will not be included in the HACCP plan. The challenge is to determine what hazards are truly significant weighing both risk and severity.

**Identify control measures** – For each of the remaining hazards, an adequate control measure must be established. These controls are to eliminate or reduce either the likelihood or the severity of the hazards.

**Principle 2: Determine the Critical Control Points**
A critical control point (CCP) is defined as a point, step or procedure at which control can be applied and a hazard can be prevented, eliminated, or reduced to an acceptable level. This differs from a control point, which is a less specific and less important step in the process.
The selection of CCPs is aided by the use of a CCP Decision Tree. Numerous versions of decision trees have been developed to assist in the determination of CCPs. Each of these decision aids has been designed to help identify what is truly a critical control point rather than just a control point. Keep in mind that no decision tree will be perfect and should never be used as a substitute for expert knowledge.

Only points at which significant product safety or functionality issues can be controlled are considered as critical control points. One critical control point can be used to control more than one hazard. Likewise, more than one CCP may be needed to control a hazard. Often the best place to control a hazard is at the point of entry, however this rule of thumb doesn’t hold true in every situation.

**Principle 3: Establish Critical Limits**

Critical limits are important tools that help the HACCP Plan to function properly. Critical limits serve as boundaries (maximum and/or minimum levels) for each CCP. Examples of Critical limits are the ranges associated with measures such as temperature, time, moisture, pH, etc. Each CCP must have one or more critical control limit to prevent, eliminate or reduce a hazard to an acceptable level. Whenever the process deviates from these critical limits, a corrective and preventive action must be taken to assure safety.

Most firms establish Operating Limits that are set within the Critical Limits. Process operators monitor the operation to ensure that it remains inside of these operating limits. In the event, that there is a trend identified for the operation to be outside of its operating limits, then the operator would make adjustments to bring the process back into control based on process control limits. In this way, the process should remain operating within the Critical Limits at all times and eliminate the need for product rework or destruction.

Critical Limits are different than factors or specifications that may affect quality. For example, the flavor of a cooked frankfurter may be best at a certain endpoint temperature, but the safety of the product may not be assured until a much higher temperature.

In many cases, the appropriate critical limit may not be readily apparent or available. Tests may need to be conducted or information gathered from experts or other resources. A conservative value should be selected based on reliable information. The rationale and reference used to establish a critical limit should be retained as supporting documentation for the HACCP plan.

**Principle 4: Establish Monitoring Procedures**

CCP monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future verification. Monitoring is focused on keeping the process under control and preventing potentially hazardous conditions (those outside of the critical limits) from developing. If the critical limits are exceeded, then monitoring will provide the information necessary to implement the appropriate corrective or preventive action.

Monitoring is best performed in real-time, so that any corrective actions can be taken quickly to minimize any negative outcomes such as non-conforming product, downtime, etc. Therefore, consideration should be given to finding rapid monitoring methods that provide a reasonable level of accuracy to support the decisions to continue with production. Monitoring methods should be practical to implement, and should be continuous whenever possible.

Selected methods should demonstrate that the control measures utilized by the company are working and remain within the critical limits. Monitoring may include measurements of a characteristic of the product or the process. Generally, physical and chemical measurements are preferred methods for monitoring. Monitoring methods must be performed with sufficient frequency to provide meaningful and timely data allowing personnel to react when necessary.

The responsibility for performing monitoring activities must be clearly assigned to capable and qualified individuals. Usually companies look for methods that can be performed by line personnel and equipment operators since they are continuously viewing the product and/or equipment and can readily observe any abnormal changes.

**Principle 5: Establish Corrective Action**

Operating outside of critical limits is regarded as a deviation requiring a corrective action. It should be anticipated that deviations will occur regardless of the employee expertise or equipment capabilities related to the operation. Appropriate plans for the corrective actions to be taken for each deviation should be developed. These plans should include actions addressing the:

- Disposition of non-conforming product
- Cause for the deviation so that the process is brought back into critical limits
- Records to be created related to the deviation and is subsequent corrective actions
- Review and updating of the HACCP plan based on new information.
By developing these action plans in advance, a company is preparing itself to minimize the effects of any deviation. Employees should also have the directions they need to make necessary adjustments to bring the operation back into control before critical limits are exceeded.

**Principle 6: Establish Verification Procedures**
Verification is the process of reviewing objective evidence for the purpose of evaluating the control status. There are many verification activities that should occur, and a company is expected to provide its employees with sufficiently detailed procedures for these activities. Verification activities include reviewing: the calibration records for all equipment or instruments; the testing methods used for analysis; the reported test results; and validation reports for equipment and processes when testing methods are inadequate.

**Principle 7: Establish Record-keeping and Documentation Procedures**
The final HACCP Plan and its supporting records must be available at the facility. Adequate records of what CCP monitoring was performed and what corrective actions were taken when critical limits were exceeded are essential for demonstrating to customers, assessors, or regulators that the HACCP Plan has been effectively implemented.

Records should be made each time the effectiveness of the HACCP plan is verified through audits, inspections, or continual review. When changes are needed to the HACCP plan, they should be made following the company’s document control process.

**Lisa M. Brown, RAC** is the President of q.s. Consulting, Inc., a full-service consulting firm specializing in the implementation of quality systems. With over ten years of experience, Ms. Brown has assisted many facilities in achieving compliance to the requirements of FDA or DEA regulations, as well as the ISO standard and other international requirements. She has previously worked as a Quality & FDA Compliance Consultant for Roche Diagnostics Corporation and Boehringer Mannheim Corporation, and as an Analytical Chemist for Quad Pharmaceuticals. Ms. Brown has achieved a number of industry certifications, including RAB’s Lead Assessor, RAP’s Regulatory Affairs Certified, ASQ’s Certified Quality Auditor and Certified Quality Manager, HACCP Trainer, and Ball State’s Certified Training Consultant. She is currently serving as Vice President of Education for the Indiana Medical Device Manufacturers Council (IMDMC). Ms. Brown received her B.S. and M.S. degrees from Kansas State University in Foods and Nutrition Science.

**Publicity Information Needed**
The Section is looking for the e-mail addresses or FAX numbers of those publications in the area that publish free community calendars. This will provide another medium for announcing Section meetings, courses and activities to various parts of the Section's membership area. These listings do not have to be restricted to the metropolitan Baltimore area. They may include anywhere within the area where quality people may receive Section information. Please forward this information to:
Bill Barton (WEBarton@aol.com) and to Elaine Wilhelm-Hass (EWilhelm-hass@sierraMILITARY.com).

**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 business professionals at large by providing opportunities for professional development, serving as a resource for managing quality in the Maryland community.

**ASQ's Each One Reach One Drawing**
Invite your colleagues to become members and win one of four prizes in ASQ's Each One Reach One program. Recruit at least two new members before December 31, 2000, and be entered into a drawing to win a Palm Computing® connected organizer or an all expense paid trip to the 55th Annual Quality Congress (AQC). Each member recruited after the initial two will give you an extra chance to win. The drawing will take place by January 31, 2001.

**Two members will win a Palm™ connected organizer.** The pocket-sized Palm™ connected organizer gives instant access to most important data. They keep track of thousands of names, addresses, appointments, to-do's, memos, email, and can even be connected to your desktop computer.

**Two members will win a free trip to AQC.** AQC will be held in Charlotte, NC, May 2001. AQC trips will include up to $600 roundtrip airfare, a 4 night stay in designated conference hotel, and full AQC registration fee plus banquet and awards luncheon.
AQC trips must be taken within the same year. No substitutions. Prizes are not redeemable for cash or membership renewals. Enrolled student members are not eligible. For more details, visit www.asqnet.org <http://www.asqnet.org>. Click Member Services. To
find out how many members you have sponsored, please contact Linda Zysko at lzysko@asq.org or call her at 800-248-1946 or 414-272-8575, extension 7643.

Visit the New ASQ e-Learning Center -- Win Fabulous Prizes!!

It’s here! The ASQ e-Learning Center is open and you’re invited to check it out. The center will feature Web-based training on a variety of quality-related topics, including standards, basic quality skills, service quality, train-the-trainer, health care, leadership, and education. Leading off at our launch are “Quality 101 Web-Based Training” and “Key Differences Between ISO 9001:1994 and ISO 9001:2000.”

And, in thanks for paying us a visit, we’re running an “e-Contest” right at the site, from October through November, and giving away a total of eight fabulous prizes.

You’ll find it all at http://www.asq.org/e-learning

The e-Contest is a short trivia about the new e-Learning Center that will automatically enter you into the e-Contest. Here’s what you could win:

Grand Prize: An all-expense-paid registration and trip to the 55th Annual Quality Congress (AQC) in Charlotte, NC, in May 2001

2nd Prize: A free registration to the ASQ public course of your choice

3rd Prize: A free edition of the ASQ Self-Directed Learning Program (CQE, CQA, or CQMgr) of your choice

Five 4th Prizes: A $50.00 certificate for Quality Press books or merchandise

Please note: The courses in the e-Learning Center will always reflect what you, our customers, tell us you want and need. Check back regularly for new offerings. You can be sure that any course you see in the center has passed a rigorous screening and review process by ASQ, assuring you of its high quality and its outstanding potential to enhance your business performance.

Do you have a training program you’d like accepted into the ASQ e-Learning Center? Contact Megan Voss at 800 248-1946, or at mvoss@asq.org for complete details!

The contest ends November 30th. Winners will be drawn December 1, 2000, and will be notified by mail.

"Achieving ISO Registration for Sollers Point/Southeastern Technical High School"

Edward Parker, Principal, Sollers Point/Southeastern Technical High School

Mission Statement: Sollers Point/Southeastern is committed to inspiring students to achieve their educational and career goals.

Quality Policy: Sollers Point/Southeastern will deliver a technical and academic curriculum in a learning environment conducive to improving student achievement.

Our Product: Baltimore County Public Schools Essential Curriculum

Our Customers: Our Students

Our Stakeholders: Our parents or caregivers, our community, our business and industry partners, higher education, and society in general.

Sollers Point/Southeastern Technical High School is the first school in the state of Maryland and the first Technical school in the nation to achieve ISO 9002:1994 registration. We have gained the respect of our business partners, our community, and even our educational system; which at first did not fully understand ISO and why we were undertaking such a process.

It has created a much more open institution, a central focus for the day-to-day operations, and has empowered everyone to become an important player in delivering Baltimore County's Essential Curriculum, our intangible product, to our customers, which are of course our students.

ISO 9000 Consortium Program

1. The three must important reasons Sollers Point/Southeastern decided to pursue ISO:
   • Quality benefits
   • Market advantage
   • Customer demands/expectations

2. The three most significant EXTERNAL benefits since choosing to implement ISO Quality System:
   • Higher perceived quality
   • Competitive advantage
   • Increased customer demand

Quality improvement - Actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organization and its customers.
3. The most significant INTERNAL benefits since choosing to implement ISO Quality System:
   - Greater quality awareness by employees
   - Enhanced communication
   - Better documentation
   - Increased efficiency/productivity

4. Items that constituted the greatest barrier to implementing the ISO 900 Quality System:
   - Document development
   - Procedure creation
   - Implementation of corrective action/Internal audit
   - Registrar selection
   - Conflicting interpretations
   - Employee resistance/one-third theory
   - Time for personnel to develop written/flow chart procedures

5. Difficulties Sollers Point/Southeastern Tech faces in maintaining or registration:
   - Maintaining interest level
   - Keeping documentation up-to-date
   - Training requirements
   - Employee turnover

6. How did Sollers Point/Southeastern Tech promote ISO?
   - Announcement letter
   - Incorporated ISO status and registration logo into letterhead/business cards, etc.
   - Invited the world, including the news media and all stakeholders, to a gala celebration

7. To what extent has ISO impacted our business?
   It has had a very positive effect!

8. To what extent would you recommend the ISO consortium to your colleagues?
   Absolutely! It provides structure, assistance, a reasonable timetable, speakers, examples and a review of documentation and practice audits.

9. In what ways did the consortium program most help Sollers Point/Southeastern Tech with its registration?
   - It provided schedules to keep us on track, access to professional consulting, access to high quality training opportunities, the ability to network and learn from others while reducing cost for training.

10. Special story:
    There was only a 1/3 buy-in until peers had the external two-day training.

**What are our Goals?**

- Establish a quality system that focuses on student and community needs.
- Establish an instructional framework to focus on the quality processes so that the culture of the staff will guarantee student success.
- Establish a methodology measurement and accountability.

**Divisions Corner**

The Chemical and Process Industries Division or CPID as it is commonly called, has roots as far back as 1950. They were chartered as a Division in December 1952 and in the spirit of continuous improvement, have been growing ever since. The current roster lists approximately 3500 members.

CPID is a very active organization that offers many opportunities to their members. If you are looking to form networks with others in similar industries dealing with issues you face regularly, volunteering for some of the Division's many activities is a great place to start. Some current CPID highlights include the following:

- Chemical Interest Committee – This group has authored several well-known books including the “Little Red Book” and “Little Gray Book”, available through ASQ Quality Press.
- Quality Assurance for the Chemical and Process Industries, 2nd edition
- Specifications for the Chemical and Process Industries

Currently, the committee is busy with a new concept with the working title; Measurement System Says Trust This Number, You Ask 'Why Should I?'

- Fall Technical Conference – CPID co-sponsors this event with the Statistics Division of ASQ and the Section on Physical & Engineering Sciences of the American Statistical Association. This October conference is focused on the latest technical developments in the statistical field. The program includes several pre-conference short courses.
- Annual Quality Congress – The Division sponsors several sessions at this May conference. We also maintain an information booth in the exhibit area.
If you would like to become involved in one of these activities, or just want to get better acquainted with the Division, please visit on-line at www.epid.net.

Division Name Change

The Public Service Network Division has decided to change their name to one more descriptive of their area of interest. The Division will now be known as the Government Division, ASQ.

Information Technology Excellence Symposium

The Johns Hopkins University Applied Physics Lab, in conjunction with ASQ - Sections 509, 511, ASQ Region 5, Quality Assurance Association of Maryland (QAAM), Society for Software Quality (SSQ), Software Process Improvement Network (SPIN) - DC Section and Maryland Section, and Q-Labs will present an Information Technology Excellence Symposium on Wednesday February 14, 2001 at the Johns Hopkins University Applied Physics Laboratory, Columbia, MD.

The goal of the Symposium is to promote excellence in today's fast pace development environments within the greater Maryland, Virginia, DC area to encompass the following disciplines:

- Quality
- Management
- Software Engineering
- Process Development

Sessions will include topics on:

- CMMI
- Security
- New Technologies

Preliminary Program Offering

8:00-8:45 a.m. Registration
8:45-9:10 a.m. Welcome
9:15-10:45 a.m. Session 1 - CMMI
10:45-11:00 a.m. Break
11:00-12:30 p.m. Session 2 - Security issues
12:30-1:25 p.m. Lunch

Lunch will be served in the APL Cafeteria at a discounted price but is not included in the symposium fee of $30.

1:30-3:00 p.m. Session 3 - New Technologies
3:05-3:30 p.m. - Closing Remarks
(Each Session will consist of two presentations.)

DIRECTIONS: Johns Hopkins/APL, Columbia, MD
From Baltimore, I-95 South to MD 32 - West. Go 2.5 miles to US Route 29 South. Take 29 for 1.5 miles to Johns Hopkins Rd. APL is located on the right just past the service station. Take 2nd entrance to Bldg. # 1.
URL: http://www.jhuapl.edu/public/visit/locat.htm

For More Information: Joel Glazer, 410-765-2346 or joel_glazer@mail.northgrum.com

REGISTRATION FORM

Name: _____________________
Address: __________________
____________________________
Phone: ____________________
Email: ____________________
Affiliation: (circle one)

ASQ 502, ASQ 509, ASQ 511
QAAM, DC-SPIN, MD-SPIN
SSQ, Q-Labs, Other

Mail this form with a check for $30 payable to: American Society for Quality, Section 509 at the following address:
American Society for Quality
Washington Section 509
PO Box 2742
Kensington, MD 20891-2742

Future Annual Quality Congress Dates/Sites

May 7-9, 2001 (55th AQC)
Charlotte Convention Center
Charlotte, North Carolina

May 20-22, 2002 (56th AQC)
Colorado Convention Center
Denver, Colorado

May 19-21, 2003 (57th AQC)
H. Roe Bartle Hall
Kansas City, Missouri
Area Quality Contacts

The following is a list of contacts of the Baltimore-Washington-Northern Virginia Partnership for Learning and Cooperation. Member organizations: Association for Quality and Participation (AQP) Capital and Chesapeake Chapters; American Society for Quality Sections 502/Baltimore, 509/Washington, and 511/Northern VA; Chesapeake Bay Organizational Development Network (CBODN); Quality Assurance Association of Maryland; the Washington Deming Study Group; the Maryland Center for Quality and Productivity; and the Society for Software Quality, Washington, DC, Area Chapter.

Association for Quality and Participation, Capital Chapter - Wayne Vick at 703-913-6513.
Association for Quality and Participation, Chesapeake Chapter - For information call 410-342-4909 visit www.bcpl.net/~pderman/aqp or e-mail AQPEmail@aol.com
Chesapeake Bay Organizational Development Network - For more information about CBODN visit www.cbodn.org
Greater Maryland Software Process Improvement Network (SPIN) - David Wood at (410) 729-0416 or visit www.mdspin.com
Maryland Association for Healthcare Quality - For more information email pattersand@juno.com
Maryland Center for Quality and Productivity - For information about the Senate Productivity and Maryland Quality Awards call the Maryland Center at 301-403-4413, visit www.bsos.umd.edu/mcq

Certification Exam Schedule

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<td>CQE/CQA/CSQE/CQIA</td>
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<td>CQT/CRE/CMII/HACCP/Quality Manager</td>
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Quality is a value judgment made at a specific junction in time

Next Newsletter Due Date January 15, 2001