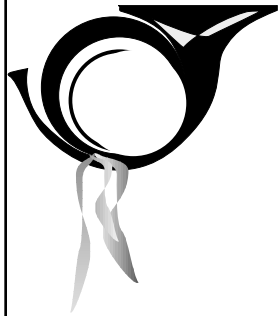


January 2001



JANUARY 18, 2001



• **Significant Changes to ISO 9001/2 A Company Perspective**

Dave Bourland is the Quality Director at **RISCO** in Highland, CA. RISCO manufactures screws and bolts for all industries. Dave's been in Quality since the Marines in 1976 where he did pre and post-flight inspections on various aircraft. Since the Marines he's been an Inspector, Senior Quality Engineer, Source Inspector, Quality Manager, DCAS Quality Representative, NAVPRO Test Equipment Specialist and Project QA Specialist, Quality Consultant, Legal Expert, ISO 9000 Registrar Auditor, and Quality Director/General Manager. Dave has been in many industries, including aircraft/aerospace, electronics, life support, medical/lab, and various metal machining & fabrication shops.

The theme of the presentation will be the "...significant changes to ISO 9001/2, from a Company perspective, and what needs to be done to implement them...as well as what the changes will mean to the Company's procedures...how to keep from burying yourself in the measurement, analysis, and improvement area's while demonstrating an understanding of the Process (versus System) Approach, and the Eight Quality Management Principles...and what do they mean by those requirements *not stated by the Customer but necessary for specified or intended use...*"

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877-SGV-0702**

Gabriel's Horn

THE OFFICIAL NEWSLETTER OF THE SAN GABRIEL VALLEY SECTION - 0702
<http://www.asq702.org>

**FROM THE CHAIR
ANTHONY IACOBACCI**

Welcome to a New Year, (New Millenium??). This year should be exciting for all, we have a new president, the stock market is down and should be on the rise, and we have an energy crisis, thank god for solar calculators.

In the coming months, our section will offer our regular dinner meetings, some interesting tours and another one-day conference. The conference is scheduled for the middle of April and is to cover the regulatory affairs, FDA, Government Regulations. More information to follow next month.

For those of you who know somebody who has not renewed their membership; please encourage them to renew. Only through expanding our knowledge will

we continue to grow and prosper. If it is something that we can be of assistance with, please contact us.

To the members who volunteer their time to the planning and execution of our section; thank you. If not for you this section would not be as prosperous as it is. Keep up the fight.

Life is a Journey – Share your Knowledge and Enjoy

Anthony Iacobacci

**NOMINATIONS FOR
2001-2002
SECTION OFFICERS**

We are currently seeking nominations for the following positions:

- Chair
- Vice Chair
- Treasurer
- Secretary

Please contact our Nominations Chair, **Dan Curtis at 310-331-1814** with your nominations or questions about nominations.

**SAN GABRIEL VALLEY SECTION 0702
2000-2001 EXECUTIVE COMMITTEE**

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<p>TREASURER Louise Deffenbaugh 626-795-2871 (H) 714-896-6429 (W) 714-896-2654 (Fax) Email: Agnes.L.Deffenbaugh@boeing.com</p>	<p>PUBLICITY Ralph Whitehead 626-339-9474 (H) 626-932-3360 (W) 626-932-3350 (F) Email: r.whitehd@cslc.com</p>	<p>WEBSITE RE-CERTIFICATION Drew Hefner 714-255-1624 (H) 310-332-8909 (W) 310-332-1879 (FAX) Email: hefnejo@mail.northgrum.com</p>	<p>ADVERTISING Open</p>	<p>EXAMINING Open</p>
				<p>STUDENT BRANCH PRESIDENT Open</p>

GABRIEL'S HORN PUBLICATION

Publisher: American Society for Quality, San Gabriel Valley Section 0702, P.O. Box 3144, San Dimas, CA 91773-7144

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Articles, advertising, photographs, and letters should be addressed to the editor.

DEADLINE: THE 25TH OF THE PRECEDING MONTH(OR 35 DAYS IN ADVANCE).

Spotlight On A Company

BIOSENSE WEBSTER

Medical Device Industry Leader Resides In Our Section

As we think of the diversity within the San Gabriel Valley, several industries come to mind relating to true applications of quality principles and practices. None can exemplify the importance of product quality better than our own Biosense Webster, a Johnson & Johnson company.

With the administration headquarters and research facility in Diamond Bar and manufacturing plant in Irwindale, BWI provides diagnostic and therapeutic cardiac catheters to the medical field throughout the world.

Cardiology Catheters are used by Interventional Cardiologists to diagnose certain types of cardiac disease. The company is also involved in various angiogenesis research programs around the world. Electrophysiology Catheters are used by Electro-physiologists to diagnose and treat cardiac electrical problems, such as arrhythmias.



The pioneer and developer of the first useful deflectable tip catheter, Will Webster began this business over thirty years ago here in the San Gabriel Valley. From early manufacturing in Baldwin Park to a newly renovated 75,000 square foot facility on Arrow Highway in Irwindale, Biosense Webster uses exclusive processes and patented techniques to craft the catheters to precise and demanding specifications.

Two necessities establish the real foundation for BWI's Quality Program. These compliance requirements are the Food and Drug Administration Quality System Regulation (21 CFR-Parts 820) and the ISO 9000 Standards. While these two disciplines are similar, there are a few differences. The FDA-QSR is directed toward the medical field with items such as environmental control and complaint files being specifically addressed. As with other regulated businesses, proper documentation is a must and careful approval and distribution of documents is key.

A significant aspect of the quality effort can be found in validation. From the design phase through manufacturing, validation is essential. Product designs, equipment, and processes all require recorded validation studies. During the recent move to the Irwindale facility, the ISO Registrar and the FDA were heavily involved in the process to verify that all areas, especially the environment, were properly validated to produce products as critical as the heart catheters.

Beyond the regulatory requirements are the activities that help to differentiate Biosense Webster's quality from other manufacturers. These activities are the Johnson & Johnson approach to Competitive Excellence. This "Signature of Quality" Program utilizes modern approaches including Six Sigma, Lean Thinking, Design for Excellence, and Dashboards. These methodologies, when applied, continue to increase customer satisfaction and overall performance across all of the business functions.

And last, but not least, noteworthy function to the Quality Program is renewed involvement with the American Society for Quality. At the recent Quality Month Conference hosted by the San Gabriel Valley ASQ, seven members of Biosense Webster's Quality Assurance staff participated and look forward to future events in which to take an active role.

*Larry Bartkus
Quality Engineer*



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COMING EVENTS 2001

MONTHLY SECTION MEETINGS

Jan ISO 9000 Changes
Feb Plant Tour - Microdyne Plastics, Inc.

For
Reservations & Info.
Call
877-SGV-0702

Note: Topics and Speakers are subject to change

CERTIFICATION/EXAMINATION

	Exam Date	Application Date
CQIA Pilot Exam	January 27	January 5
CQT/CRE/CMI/HACCP Certified Quality Manager	March 3	January 12
CQE/CQA/CSQE/CQIA	June 2	April 6
CQT/CRE/CMI/HACCP Certified Quality Manager	October 20	August 24
CQE/CQA/CSQE/CQIA	December 1	October 5

COURSES / CONFERENCES & SEMINARS

Jan 18-19 Measurement Science Conference at the Disneyland Hotel
Mar TBD Standards & FDA

For other Refresher Course information contact: San Gabriel Valley Section - Bea Ng at 626-963-2884
Inland Empire Section - Pam Locatel at 909-683-7243, Los Angeles Section - Carl Moore at 310-900-2344,
San Fernando Valley Section - Angel Luna @ 818-586-4371
or call ASQ Headquarters at 800-248-1946 for other Sections.

GLOSSARY OF TERMS IN QUALITY

Acceptance - The act of approval (usually after satisfactory completion of testing) of commodities, components or product.

Acceptance Number (Ac or C) - The largest number of defectives or defects in sample or samples under consideration that permit the acceptance of the inspection lot.

Acceptable Quality Level (AQL) - The acceptable quality level is the maximum percent defective (maximum number of defects per hundred units) for the purpose of sampling inspection that can be considered satisfactory as a process average.

Acceptance Sampling - Sampling inspection in which decisions are made to accept or reject a product; also, the science that deals with procedures by which decisions to accept or reject are based on the results of the inspection samples.

Acceptance Sampling Plan - A specific plan that states the sample size or size to be used in the associated acceptance and rejection criteria. A specific acceptance sampling plan may be developed for any acceptance situation, but inspected systems usually include sets of acceptance plans in which lot sizes, sample sizes, and acceptance criteria are related.

Analysis of Variance - A technique that subdivides the total variance of a set of data into meaningful component parts associated with specific sources of variation.

Arithmetic Mean - The sum of the individual readings or observations divided by the total number of readings or observations. This is a statistical measure of central tendency.

Assignable Causes - Factors contributing to the variation in quality, which it is possible to detect by statistical methods. Assignable causes may be identified and removed to contain statistical controls.

Attributes - An attribute is a characteristic or property which is appraised in terms of whether it does or does not exist with respect to a given requirement.

This glossary of terms will be continued in the upcoming issues of the Gabriel's Horn.

ADVERTISING RATES FOR GABRIEL'S HORN

Size	1 Issue	Yearly
Business Cards	\$ 20	\$ 200
1/4 Page	\$ 45	\$ 450
1/2 Page	\$ 85	\$ 850
Full Page	\$ 150	\$ 1500
Inserts	\$ 100	\$ 1000

Gabriel's Horn currently reaches approximately 600 Quality Professionals in Southern California each month.

If you are not currently an ASQ member of Section 0702, a subscription to *Gabriel's Horn* is available for \$14 per year.

For additional information or to place an ad, please contact:

Ralph Whitehead @ 626-932-3360

(Email: r.whitehd@cslc.com)

or leave a message with our answering service
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As we continue to upgrade and expand our collection of books and publications at the San Dimas Public Library, we also continue to ask for your tax deductible donations to help us in our effort. If you have a donation or would simply like a current list of materials available, call ASQ, Section 0702 at 877-SGV-0702 and leave your name, phone number, and a brief statement . . . we'll get back to you as soon as possible.



Remember . . . the San Dimas Library is located at 145 N. Walnut Avenue in San Dimas. For information call 909-599-6738 and for Reference/Circulation call 909-599-0060. Current library hours are as follows:

Tuesday 12:00 noon - 8:00 pm
Wednesday, Thursday 1:00pm - 8:00 pm
Friday, Saturday 10:00 am - 5:00 pm
Sunday, Monday Closed

A listing of books may be requested by contacting **Anthony Iacobacci** (see Pg. 2 for contact info)

SIX SIGMA

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PIVOT

RADICAL THINKING?

“Measuring the Unmeasurable (Fuzzy Measurements)”

You must have heard of many ‘fuzzy’ things that companies would like to measure, e.g., attentiveness to customers. This becomes especially pronounced in service industries such as the hospitality industry.

At Loews Hotel, the people rose to this challenge by creating a performance standard for this seemingly ‘fuzzy’ concept. After all, how does one improve what one cannot measure? And how does one reward performance unless one can measure it? In the hotel industry, attentiveness to customers can be a very important measurement and differentiating factor. Loews defined a service requirement for all chance encounters between a guest and staff member.

Called “10, 5, First and Last,” this requirement stipulates that hotel personnel:

- make eye contact with a guest by the time they are ten feet away,
- greet the guest no less than five feet away,
- be the first person to speak, and
- be the last person to speak in the conversation.

Although this may not be perfect for each

guest, Loews believes that the standard is a good reflection of the kind of attention that most customers want and expect at a high quality hotel.

I was recently at a client site conducting an executive session on six sigma and of the 24 people in the audience, only two were from the non-manufacturing areas! Why? Because they were not used to getting measured. We discovered that most of the ‘lean techniques’ that had been implemented at the various plants of this organization were also in manufacturing - that was what was being measured. The administrative and transactional areas were being completely neglected! Why? Those measurements were too difficult to develop or perhaps too fuzzy!

I gave my client some examples of where lean thinking could be useful in the administrative and transactional area; e.g., how companies churn out reports by the hundreds, but very seldom take the time to determine the effectiveness and usefulness of those reports! Was it that difficult to measure?

Going along this line of thinking my client agreed that in moving from ‘lean’ to

‘six sigma’ they would not be sending a wrong message. They would be building on their past successes - and the Lean experience in manufacturing.

Measuring the Unmeasurables can open up whole new opportunities for improvement - after all what gets measured, improves. Without measurements, how does one know that improvements have been made? With a bit of ingenuity, fuzzy measurements need not be fuzzy anymore!



Akhilesh Gulati

Past Chair and Senior Member of the American Society for Quality, San Gabriel Valley Section. Partner with PIVOT, a

*management consulting firm specializing in implementing Total Quality Change Strategies and ISO 9000, building on a foundation of quality. Has taught courses in Manufacturing Excellence, Information Technology, and Benchmarking & Reengineering at UCLA Extension. He also teaches Design for Manufacturing Excellence and trains Six Sigma Black Belts.
Ph: 877-pivot-mc; Web: <http://www.pivotmc.com>*

He also owns Akhil International, a printing, design and promotional products company. (See ad on back page)

EXECUTIVE COMMITTEE, AN OPEN INVITATION . . .

We extend an open invitation to all Section 0702 Members to get involved with your Section’s Management. We all have something to contribute, no matter how busy our schedules. Your Executive Committee has several openings . . . and you just might be the perfect candidate for the following position: **Newsletter Editor, Examining, Arrangements and Advertising.**

And as always, attending a Board Meeting is not a commitment to becoming an active Board Member. We still meet on the first Monday of each month (except holidays) in which case we will meet on the second Monday. The meetings start at 6 pm and remember . . . dinner is on us! If you’re interested or even the least bit curious, then please call **Tony Iacobacci**, our Section Chair at **310-320-7345** or leave a message on our *new service number* at **877-SGV-0702**. So pick up the phone and give us a call . . . you’ll be glad you did!

Meeting will be held on Monday, January 8th, February 5th at 6pm.

Our Board meeting location is at **MARIE CALLENDER’S**, 3117 East Garvey Avenue North, West Covina. Take Barranca exit north off the San Bernardino (10) Freeway . . . just look for “RESTAURANT ROW”. Phone: 626-339-5491

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A vertical banner on the right side of the page. The text "Poster Prints" is written vertically in a large, white, sans-serif font on a dark background. To the right of this text is a black and white photograph of a tall tower with a spherical top. Below the tower image, there are four overlapping CD/DVD discs. At the bottom of the banner, the text "CD DUPLICATION" is written in a white, bold, sans-serif font on a black background.

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