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Chair's Message

Happy holidays to all of you. Thank you for being part of our ECD family. You are all welcome to email us (addresses on back page) and ask any questions about ASQ and our division.

We are pleased to announce the recipient of the Ralph A. Evans Award this year is Marion Bize. She will be presented with the award at the annual Reliability and Maintainability Symposium (RAMS®), which will be held in Reno, NV, January 22 – 25, 2018.

The ECD Ralph A. Evans Award for Long-Term Exemplary Service to ECD is not granted every year. When it is awarded, it goes only to an ECD member who has provided long-term service above and beyond the requirements of whatever ECD volunteer positions they have held. RAMS is the premier event in the reliability, availability, and maintainability engineering disciplines. Make plans now to attend this exciting conference in Reno. Registration opened in July, and one of your benefits as an ECD member is a discount on registration for RAMS.

We are improving the value we provide to our members. If you have an idea, please let us know. Members matter! Your input and participation are welcomed and encouraged. Current open positions within the ECD include Standard Committee chair and ROHAS chair. For more information on these and other openings, you may contact me or another member of the leadership council. Our contact information is available at asq.org/ec.

If you would like to publish an article in this newsletter, send a completed draft to ECD newsletter editor Jay Patel (jayp@qpsinc.com). Articles will be submitted to the ECD board members for approval. Articles must be related to quality assurance/control. Articles with subject matter in direct relation to ECD will get top priority.

Keep moving forward.

Sincerely,

Lucita Kahn
ECD Chair 2017-2018

ECD Best Paper Award to Be Presented at RAMS

ECD's Best Paper Award will be presented to **David G. Fernald Jr.** at the ECD council meeting at RAMS in Reno, NV, in January.

Fernald's award-winning paper, "*When Does Performance Become a Safety Issue?*" was presented at RAMS 2017 in Orlando, FL. He is a test manager with the U.S. Army Evaluation Center (AEC).

At AEC, he has managed developmental testing and performed safety evaluations of a broad range of military systems from handheld targeting devices to missile systems. Previously, he was president and general manager of Tern Wireless (a small wireless service provider). He earned a master's degree in mechanical engineering from Stevens Institute of Technology, a master of business administration degree from Florida Institute of Technology, and a bachelor of science degree in mechanical engineering from Duke University. He is also a past chair of ASQ's Electronics and Communications Division, and has served in multiple volunteer roles for ECD over a number of years. Fernald is the general chair of RAMS 2018.

ECD's Best Paper Award is presented to the author of the best paper by an ECD member presented at either WCQI or the following RAMS. The award includes a plaque and an honorarium. RAMS grants a free registration to the winner the year the award is presented.

Congratulations to David!

Respectfully submitted by:
Charlie Plotkin and the ECD council member leaders

COME ONE, COME ALL!

ASQ North Jersey's 40th Anniversary

Spring Quality Conference

Celebrating 40 Years of Quality Excellence

March 29, 2018

ASQ North Jersey Section 304 proudly announces its 40th Annual Spring Quality Conference (SQC) to be held at the **Marriott Hanover, Whippany, NJ**, March 29, 2018.

This full-day conference offers a continental breakfast, four-course lunch, four tracks, 17 presentations, vendors, and **outstanding networking opportunities**.

The full SQC program and brochure are posted on our website. Browse the website by clicking the tabs along the top.

Join the fun and **network, network, network**, with like-minded professionals!

www.asqnorthjersey.org
www.springqualityconf.org



Keynote Speaker

*Nancy Singer, JD, ILM, RAC
Assistant Professor School of
Medicine and Health Sciences*

"Dangerous Documents: Avoiding Landmines in Your Records and Emails"

Nancy Singer founded Compliance-Alliance, LLC in 2004 to specialize in the professional development of government, associations, and business professionals. She has taught over 1,700 people how to improve their communications practices. She is on the faculty of George Washington University School of Medicine and Health Sciences. She has taught classes at Johns Hopkins University, University of Southern California, and Harvard Symposia. She presently teaches the investigators and compliance officers in FDA district offices, and the reviewers in FDA staff colleges. Previously, she served as special counsel for the Advanced Medical Technology Association. For her efforts to improve communication between the government and the regulated industry, Singer received Vice President Al Gore's Reinventing Government Hammer Award and the FDA Commissioner's Special Citation.

ASQ NEQC 62nd Conference

Developing and Sustaining World-Class
Excellence for the Global Economy

October 2018

The North East Quality Conference (NEQC) has a tradition of bringing together quality and other professionals, practitioners, and management for a total perspective on system and process improvement. Representatives from manufacturers, service, software, education, healthcare, nonprofit, and government organizations are invited to submit proposals for 60- or 90-minute presentations and mini workshops.

The program schedule and arrangements will be similar to the last seven conferences. Information is available on the website.

Location: Royal Plaza, Marlborough, MA

Keynote Speakers: There is a luncheon speaker on October 23 and 24 (must have previous keynote conference experience with proven reputation; sponsorship preferred)

Five different seminars (one-day duration):
October 12, 2018 (9:00 a.m. – 5:00 p.m.)

Five different seminars (two-day duration):
October 25 – 26, 2018 (9:00 a.m. – 5:00 p.m.)

We welcome all submissions relevant to our theme/topics as described. In keeping with the conference theme, we will give special consideration to proposals from practitioners speaking about effective practices and successful initiatives.

NEQC 2018 is the forum to capture the lessons learned from actual, real-world projects and adapt this success to the new and ever-changing global economy.

PLEASE SUBMIT TO (by email only): jayp@qpsinc.com

Jay Patel, Conference Chair

Understanding the Process Approach for ISO 9001:2015



Process Approach

ISO 9001 2015 section 0.3 expects organizations to adopt a process approach and section 5.1.1 asks top management to exercise leadership by promoting an awareness of this approach. But what is it? The process approach is a management strategy. When managers use a process approach, it means that they manage and control the processes that make up their organizations, the interactions between these processes, and the inputs and outputs that tie these processes together. It also means that they manage these process interactions as a system. When applied to quality management, it means that they manage processes and process interactions as a coherent process-based quality management system (QMS).

Process Definition

A process is a set of activities that are interrelated or that interact with one another. Processes use resources to transform inputs into outputs. They are interconnected because the output from one process often becomes the input for another process. The definition I have used for more than 15 years is “a series of steps that lead to a desired result.” This may seem less eloquent than the ISO 9000 definition, but not all processes are transformations. Many service processes entail only treating, assessing, informing, altering, or moving stuff from one place to another.

Inputs and Outputs Process

The new standard defines an output as the “result of a process” and then goes on to list four general types of outputs: services, software, hardware, and processed materials. However, ISO’s very broad definition suggests that there are many more types of outputs. If an output is the result of a process, then many kinds of outputs (results) are possible, including not only tangible outputs like products, but also intangible ones. So, outputs could include not only services, software, hardware, and

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About the Author

Jay Patel

is founder, president, and CEO of Quality & Productivity Solutions, Inc.

processed materials, but also decisions, directions, instructions, plans, policies, proposals, solutions, expectations, regulations, requirements, recommendations, complaints, comments, measurements, and reports. Clearly, an output could be almost anything. But what about inputs? Since the output of an upstream process often becomes the input for a downstream process, outputs and inputs are really the same thing.

Process Interactions

When you think about all the processes that could make up a QMS and then think about all the possible input-output relationships that tie these processes together, you soon realize how big and complex such a system is. Because of this, you may find it difficult to create a single map or diagram of your entire process-based QMS. There are just too many processes and too many input-output relationships. For this reason, we suggest that you diagram one process at a time using a single flowchart on a single page (see below). This will allow you to specify the most important input-output relationships without getting buried in complexity. The diagram below shows, in general terms, how this could be done. The box in the center is the process you want to diagram. That's your focus. Upstream processes provide outputs for the central process and downstream processes receive inputs from them. Arrows represent inputs and outputs and the associated text describes them. These arrows also show that an input-output relationship is sometimes a two-way street. Sometimes, inputs go one way and outputs go the other way.

Process-Based QMS

ISO 9001 section 0.3 introduces the concept of a process-based QMS and sections 4 – 10 explain what is needed to establish one. But what is it? A process-based QMS uses a process approach to manage and control how its quality policy is implemented and how

its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes. Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated process-based QMS.

Process Examples

Since the process approach is now central to ISO 9001, we've tried to identify the processes that could make up a process-based QMS. Some of these are listed below, and some overlap. How you define your processes is entirely up to you. Each organization's list varies significantly.

- communications
- complaint handling
- design
- development
- document control
- innovation
- internal auditing
- maintenance
- management review
- manufacturing
- marketing
- market research
- planning
- purchasing process
- records management
- service delivery assembly
- traceability
- training
- validation
- verification

This plan-do-check-act process approach is all around us. It is used for business process planning, business process management, and to determine the ability of the process system to achieve planned results—process effectiveness. Now, ISO has incorporated it into the newest requirements.

MEET OUR TEAM

ECD Leadership Roster

Immediate Past Chair

Marion Bize

Richardson, TX
Email: mbize.tl9k@gmail.com

Chair

Lucy Kahn

North Bergen, NJ
Email: lkahn3@verizon.net

Chair-Elect

Melvin Downes

Email: mcam@optonline.net

Treasurer

Marc Kelemen

Avon, OH
Email: nanomarc@wowway.com

Secretary

Alison Solomon

Ada, MI
Email: jeepwife07@gmail.com

Volunteer Opportunities:

Please consider volunteering to serve the ECD in some capacity. Vacant positions are identified below. Email anyone on the leadership roster for more information on how to volunteer.

- *RoHS Committee chair*
- *ECD operations manual chair*
- *Some ECD regional counselors*
- *ECD section representatives*
- *Nanotechnical Committee discussion board and blog chair*
- *Writing articles for our newsletter and other opportunities*
- *Speaking at section events*
- *Speaking at conferences*
- *Other (please specify)*

If additional candidates for the remaining positions are identified by submission of petition signed by 10 regular paid members, then an election will be held.

Such petitions, if any, shall be submitted to Marion Bize, current immediate past chair and Nominating Committee chair at mbize.tl9k@gmail.com no later than September 30, 2018.