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# Are You Ready to Learn Something?

*Let's get out there and broaden our horizons!*

Summer is soon coming to a close and with that brings cool, crisp fall temperatures along with beautiful colors as the leaves change. Unfortunately along with the fall weather we get shorter days. Since we can't get outside and enjoy our interests as much what are we supposed to do with ourselves? Well, we can always learn something new!

This issue of our newsletter focuses on education. We have a new section featured titled "Ask the SME!" where a section subject matter expert can help explain a quality tool, answer reader questions, or just advise members about changes in the Quality field. In this inaugural section we have a rundown of changes to four popular standards written by our own Ed May. We also have a message from the Education Committee to let us know what sort of classes are on offer, as well as an announcement for an exciting class starting soon covering business process management!

If today is a great day to learn something new we truly hope that you take advantage of the offerings Section 304 has to advance your skill set and possibly your career!

The Executive Board hopes that you enjoy this issue of the newsletter, and we welcome your thoughts and comments for future issues.

If you are interested in submitting to the newsletter please contact the newsletter editor Michelle Carezza via email at [vmcarezza@gmail.com](mailto:vmcarezza@gmail.com) and as always feedback for continual improvement is most appreciated!

This newsletter is designed with you, the membership, in mind. Please let the editor know what you would love to see featured!

## Message from the Chair

So you must be wondering what your executive board does during summer hiatus. Here is what we have been preparing for:

It's that time of the year again. We are starting a new 2017-2018 season. Our fall, winter and spring general section meeting (GSM) schedule is almost full. As usual, we are going to bring wonderful speakers and a plant tour.

We are also in a process of building a new website for our section. I am very hopeful that we should be able to bring new helpful features for our members. We welcome suggestions from you while we create the new features.

Before we know it, Spring Quality Conference (SQC) will arrive in March. Our SQC committee is working very hard to bring excellent speakers for the conference. SQC - 2018 will be our 40th anniversary.

As always, we are looking for new members to be added to our executive team. Please feel free to contact me at [mulraj.ved@gmail.com](mailto:mulraj.ved@gmail.com) or any of our other committee members. We need you, but it will be equally rewarding for you too. It's my promise.

As I mentioned last time, with this newsletter, we hope to reach out to our members and supporters every quarter. Past members, members from other sections and friends can also keep in touch with the section through Facebook, Twitter, and our new website.

We hope that all these resources will provide you with ways to remain connected to our section and to continue to offer your support.

Hope to see you soon in our general section meeting.

Best regards,

*Mulraj Ved*

## Ask the SME!

This section of the newsletter is designed to feature an article by a section subject matter expert (SME) to answer your quality questions, discuss changes happening in the field, or to explain a quality tool. This issue we are featuring an article from our own Ed May covering recent changes in four familiar quality management system standards. Please contact Michelle Carenza via email at [vmcarenza@gmail.com](mailto:vmcarenza@gmail.com) to voice what you would like to see discussed in upcoming issues!

A Comparison of the Recent Changes in Four Quality Management System Standards: ISO 9001, AS 9100, IATF 16949, ISO 13485 By Ed May, Director of Quality and Productivity Solutions in New Jersey

Many organizations are currently transitioning to the latest revisions of four major Quality Management System Standards.

1. ISO 9001:2008 is being superseded by ISO 9001:2015.
2. AS 9100C:2009 is being superseded by AS9100D:2016.
3. ISO/TS 16949: 2009 is being superseded by IATF 16949:2016.
4. ISO 13485:2003 is being superseded by ISO 13485:2016.

Justifications for the revisions and transitions include: Taking a more Holistic Approach, Harmonization with other standards, Standardization of clause numbers, making standards more relevant to Services, taking into account Technological changes, and various Global considerations.

ISO 9001:2015 which is appropriate for any organization producing goods and services leads the changes. It is structured according to "Annex SL" which took this standard from 8 to 10 clauses. It added: Context of the Organization, Interested Parties, Risk Based Thinking, and Organizational Knowledge. It made the Process Approach more explicit. It limited exclusions. It added new definitions and changed old definitions. It no longer requires a Quality Manual, Management Representative or Preventive Actions.

AS9100D:2016 is for organizations that design, develop and provide Aviation, Space and Defense products and services, and post-delivery activities, including maintenance, spare parts, and materials for their own product and services. This standard embraces ISO 9001:2016 except that it still requires a Management Representative and suggests use of a Quality Manual. It offers new and modified terms and definitions. It includes useful Notes and Examples. It adds separate clauses for Product Safety and Counterfeit Parts Prevention. It requires consideration of Human Factors when dealing with Nonconformances and Corrective Action. It clarifies Configuration Management, enhances Awareness, and emphasizes Ethical Behavior.

IATF 16949:2016 is for Automotive Production and relevant service parts organizations. It embraces ISO 9001:2015, except that Preventive Action is still required. It offers new and modified terms and definitions. It adds separate clauses for Product Safety and Warranty Management. It clarifies Manufacturing Feasibility and enhances the clause on Products with embedded software. It emphasizes Auditor Competency.

ISO 13485:2016 is for organizations that design and manufacture medical devices and in-vitro diagnostic devices as well as related processes and services. It is built upon ISO 9001:2008 but it's new and modified terms and definitions are consistent with ISO 9001:2015. It assumes that every time it uses the word "appropriate" that the clause is appropriate unless you show otherwise. Changes from the old revision are incorporated in: Supply Chain and Outsourcing, Post Market Information Gathering, Adverse Event Reporting, Design Verification / Validation, Design Transfer, Complaint Handling, Handling of Returned Product, Environment Controls, Process Validation, Records Management, Annex Z (related to European Directives), Product Lifecycle Management, Emerging Markets, and Risk Management.

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## Ask the SME! (continued)

Organizations making one or more of these transitions should already be updating their documented information, doing training, and conducting internal audits to the new standard(s). They should be setting dates with their Quality Registrars for the Certification Audits. Time is short. Quality Registrars are eager to conduct your Certification Audit well before your old certification lapses, so that you have time for any required Corrective Actions.

[This article was written by Ed May, ASQ CSSBB, CQE, CQA, CMQ/OE, CSQP. Ed is a Senior Member of ASQ. He has been a member of Section 304 North Jersey for 30 years, on the Section Board for 20 years, and active on the Spring Quality Committee for 10 years. He serves a Scholarship Chair. Ed is the Director of Quality and Productivity Solutions, Inc. (QPS) in Woodbridge New Jersey. He recently gave a series of Free Friday Evening Lectures on the Changes in each of the cited standards. His article is based upon PowerPoint Presentations created by QPS HQ in Marlborough, Massachusetts. Reference: [www.qpsinc.com](http://www.qpsinc.com). Thursday, July 13, 2017

## Message from the Education Committee

Our ASQ North Jersey Section 0304 Education Committee provides class-room training on a variety of quality topics so that our members may increase their technical knowledge and also achieve their ASQ certifications.

***Our Mission is to help Knowledge Workers increase their Productivity!***

Let us become a technical resource to you as an individual or alternatively to the teams at your current organization. We can provide you with economical and effective training, through our publicly conducted classes, or through specifically tailored courses held on-site at your organization's facility.

Our offerings include both ASQ certification exam preparation as well as subjects of importance for today's quality professionals. All courses are conducted locally by senior ASQ members who have each achieved multiple ASQ certifications and who have demonstrated proficiency in the area under discussion.

Currently our most popular courses are as follows:

### SQ certification prep:

CSSGB (Six Sigma Green Belt)  
CSSBB (Six Sigma Black Belt)  
CQA (Quality Auditor)  
CQE (Quality Engineer)  
CPGP (Pharmaceutical GMP Professional)  
CMQ/OE (Quality Manager/Operational  
Excellence)

### Other popular courses:

- Business Process Management Introduction: An aid to understanding the Process Approach Requirements in ISO 9001:2015
- Design-of-Experiments
- Statistical Process Control
- Inspector's Workshop
- Quality-by-Design
- Continual Improvement using Process Behavior Analysis
- Design for Six Sigma (DFSS)

For more information, please contact:

Carl Perini, Education Committee Chairperson  
American Society for Quality, North Jersey Section 0304  
PO Box 4961, Wayne NJ 07470  
Phone: 973-616-4371  
E-mail: [cperini@asqnorthjersey.org](mailto:cperini@asqnorthjersey.org)

# ASQ North Jersey Course Announcement

## **“Business Process Management Introduction: An aid to understanding the Process Approach in ISO 9001:2015 and ISO 13485:2016 Medical Devices”**

(2.5 CEU and ASQ RUs will be awarded)

Course runs on Saturdays beginning October 21, 2017 thru November 18, 2017.



Instructor: Nancy S.Q. Chang  
MBA, ASQ-CSSBB, ABPMP-CBPP

### ***Abstract***

As organizations transition to ISO 9001:2015 or ISO 13485 Medical Devices Standard, adopting the process approach will be essential. For many organizations, process activities are interrelated and span horizontally across functional boundaries. Understanding how processes are interrelated will foster communication between process owners and cross-functional teams to resolve quality issues across linking functions. This course provides foundational concepts to enable participants to better understand the process approach to quality management for meeting customer requirements.

For registration, as well as onsite courses, contact Carl Perini, Education Committee Chairperson via phone at 973-616-4371 or via email at [cperini@asqnorthjersey.org](mailto:cperini@asqnorthjersey.org).

## 2017 Inspector of the Year Award Call for Nominations Now Open!

Nominations are now being accepted for the 2017 Bob Pennella Inspector/Technician of the Year Award. This award was reinstated in 2016 to promote quality involvement in non-managerial positions. Any quality inspector or technician can nominate themselves, or they can be nominated by someone else. The only requirement is that the applicant performs as a quality inspector or technician at least 50% of their time.

The award will be presented during our December 2017 general section meeting. The award consists of a commemorative plaque and a cash award. Nominations must be received no later than October 31, 2017.

Section 0304 would like to congratulate once again our 2016 winner Victor Leyn!!

Please contact Michelle Carezza, Pennella award chair, via email at [vmcarezza@gmail.com](mailto:vmcarezza@gmail.com) for more information and to receive the award application and nomination information.

## Upcoming Section Meetings

General section meetings are on the third Wednesday of each month. Meetings begin at 6:00pm with networking, dinner is served at 6:30pm, and the program begins at 7:00pm.



Contact our Arrangements Chair via email at [reservations@asqnorthjersey.org](mailto:reservations@asqnorthjersey.org) for more information and to RSVP.

Please include your membership number, company name, and telephone number in the e-mail.

*Interested in being published in our next newsletter? Contact Michelle at [vmcarezza@gmail.com](mailto:vmcarezza@gmail.com) for more information!*

*Follow us at @ASQ\_0304 on Twitter!*

*Thank you for reading, and until next time continue to dream, aspire, and achieve!*



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Section  
The Global Voice of Quality™

