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MESSAGE FROM THE CHAIR

On March 22, 2024, the Granite State Section held a joint meeting hosted by the Vermont Section. The speaker was Robert Freeman, a member of ISO/TC 176/SC 2/WG 29 “Revision of ISO 9001”. His presentation was “ISO 9001:2025 A Preview of What’s to Come!” He had a short presentation outlining the schedules and some of the major issues. He took the time to answer many questions and explained the process to discuss and decide on changes. The online meeting had the largest number of participants for the Vermont section.

March 27, 2024, saw the first in-person meeting of the Granite State section. Dan O’Leary spoke on “Understanding Attribute Lot Acceptance Sampling Plans”. He explained the use of ANSI Z1.4 and the c=0 sampling plans revised by ASQ last year. Participants had copies of the tables and walked through examples. In addition, the presentation included an explanation of the binomial distribution and how it applies to attribute sampling.

Granite State is partnering with nearby sections to hold joint meetings. This can help bring a variety of topics to the members.

The Merrimack Valley, Vermont, and Worcester sections have invited Granite State members to join their meetings, even if they are not joint meetings. Close cooperation with nearby sections will help provide educational opportunities for Granite State members as well as RUs to support recertification. This newsletter will provide the information when available.

The Worcester section will conduct ASQ certification exam courses for CQA, CQE, and CQT. See the information below.

The SLT continues to use its communication channels to members including myASQ, the section website, <https://www.asq104.org/>, and newsletters. In addition, items from myASQ are in the ASQ Daily Consolidated Digest which goes to your inbox.



The section is planning a number of events which are described below. We look forward to member attendance.

The Section Leadership Team, SLT, is looking for new members. See SLT Members Needed below for the open positions. This is a good opportunity to help the section and support your recertification.

The section welcomes members who can make a presentation at a dinner meeting or write an article for this newsletter. In addition to contributing to the section, these activities can help support your recertification.

Dan O’Leary CMDA, CQA, CQE, CRE, CSSBB

GRANITE STATE MEMBER MEETINGS

April Meeting

Andy Moysenko on Wednesday, April 24, 2024, will speak on “Causal Loop Diagrams”. This is an in-person meeting which will be held at the Puritan Backroom – Manchester, N.H. If you want dinner at the Granite State price, then buy a ticket (\$25.00) and order off the menu. There is also a free non-dinner option for which you should get a ticket. The section will raffle off a copy of *The Fifth Discipline* by Peter Senge.

Networking from 5:30 pm to 6:00 pm

Dinner is from 6:00 pm to 7:00 pm and is ordered off the menu

The presentation is from 7:00 pm to 8:00 pm

May Meeting

Speaker and topic under development. This is an in-person joint meeting with NH SME which will be held at the Puritan Backroom – Manchester, N.H. If you want dinner at the Granite State price, then buy a ticket (\$25.00) and order off the menu. There is also a free non-dinner option for which you should get a ticket. The section raffle is not yet decided.

Networking from 5:30 pm to 6:00 pm

Dinner is from 6:00 pm to 7:00 pm and is ordered off the menu

The presentation is from 7:00 pm to 8:00 pm

June Social

Granite State Day at the ballpark. A chance to attend a baseball game – Richmond Flying Squirrels v New Hampshire Fishercats – on Sunday, June 16, 2024, in Manchester, NH. The game starts at 1:35 pm. Your ticket includes a meal coupon for a hot dog and drink. Our members +1 will enjoy this social at no cost. Arrive at 1:00 pm.

June Joint Meeting with the Worcester Section

Dan O’Leary, Granite State Chair, on Thursday, June 20, 2024, will speak on “Medical Device Risk Management”.

Time: 12:00 PM to 1:15 PM

Zoom link <https://us02web.zoom.us/my/qpsinc>

Meeting ID 7906904984, no passkey required



Registration: Not required, just attend

GRANITE STATE EDUCATIONAL EVENT

Spring Event

Still in the planning stage.

NEARBY SECTION EVENTS

Merrimack Valley Section

April 24, 2024 – Plant Tour at Masimo Semiconductor 25 Sagamore Park Rd., Hudson, NH 03051

Time:

5:45-6:00 pm Registration

6:00 – 6:45 Tour

6:45 – 7:45 Dinner/networking

Cost: \$25 with dinner, catered from a local restaurant

Registration information: <https://app.memberplanet.com/#/event/asqmerrimackvalleysectioncommittee/tourofmasimosemiconductor>

Vermont Section

April 23, 2024 – Engaging Students in Quality Learning-Student Report on Lean Six Sigma

Time: 12 Noon - 1:00 pm (EDT)

Cost: This webinar is FREE and open to non-members

Registration information: <https://asq.webex.com/weblink/register/r4d3e2cb3c5e0dfd79a563786c3da7fb3>

Worcester Section

May 16, 2024 – “Unlocking ISO 9001 Secrets: Strategic Integration” by Don Brecken, ASQ Fellow

Time 12:00 pm to 1:15 pm

Zoom link <https://us02web.zoom.us/my/qpsinc>

Meeting ID 7906904984, no passkey required

Registration is Not required, just attend

June 20, 2024 – “Medical Device Risk Management” by Dan O’Leary, Consultant & Trainer

This is a joint meeting with Granite State

Time 12:00 pm to 1:15 pm

Zoom link <https://us02web.zoom.us/my/qpsinc>

Meeting ID 7906904984, no passkey required

Registration Not required, just attend



NORTH JERSEY QUALITY CONFERENCE

The North Jersey section will hold an all-day conference “The Future of the Quality Profession: Evolution or Extinction” by Zoom on Thursday, April 18, 2024. Conference attendees will receive 1.0 RUs. To register go to www.asqnorthjersey.org

The conference agenda is:

8:00 am Zoom opens

8:30 am Welcome – Opening Remarks by Ed May, ASQ Section 304 North Jersey Chair

9:00 am “The Powerful Role of Quality in Customer Experience” by John Goodman

10:00 am “Process Behavior Using Distributions (A Reboot of the late Carl Perini’s Classic Presentation)” by Ed May

10:30 am “An Introduction to ASQ Section 304 North Jersey’s upgraded E-commerce Website and the Upcoming Virtual Mini-Classes and Quality Courses” by Ed May

11:00 am “Through the New Lens: Quality and Process Improvement Through the Lens of Complexity” by Bruce Waltuck

12:00 Noon “State of the Quality Profession (In a World Without Work)” by Greg Hutchins

1:00 pm “Strategy and Tools for Transformation Leaders – Align Strategy, Culture, Customer Experience, Human Performance, and Success” by Tony Belilovskiy

2:00 pm “Where Will Quality Be in the Next Five Years?” by Grace Duffy

3:00 pm “What Leaders Owe” by Mike Vella

4:00 pm “Technology and Business Efficiency – A Solution to the Quality Problem?” by Jim Wade

5:00 pm Closing Remarks by Ed May, Section 304 North Jersey Chair

5:30 pm Zoom Closes

ASQ CERTIFICATION EXAM SCHEDULE

Certification: CQA, CQE, CQIA, CSQE, CSSGB, CQPA, CCT, CPGP

Application Deadline: May 12, 2024 Testing Window: June 1 - 30, 2024

Certification: CQT, CQI, CRE, CFSQA, CMDA, CMQ/OE, CSSBB, CSSYB, CSQP

Application Deadline: June 9, 2024 Testing Window: July 1 - 31, 2024

Download the *ASQE Candidate Handbook and Application Process* from <https://p.widencdn.net/j5hi1o/Certification-Candidate-Handbook>

WORCESTER SECTION ASQ CERTIFICATION EXAM COURSES

Worcester Section is planning three ASQ certification exam courses for May and June 2024.

For registration contact Raj Kasbekar at rkasbekar@gmail.com You must pay by check payable to ASQ before May 1, 2024. Even if there are only 2 students, the classes will run.



Course	CQA	CQE	CQT
Duration	8 weeks via zoom from your home	8 weeks via zoom from your home	8 weeks via zoom from your home
Weekly, Start Date	Tuesday, May 7, 2024	Wednesday, May 8, 2024	Thursday, May 9, 2024
Time Start-End	6-8 PM	6-8:30 PM	6-8 PM
Cost (Buy your own materials)	\$400	\$500	\$400
Classes coverage	Entire Body of Knowledge plus 300 questions practice	Entire Body of Knowledge plus 300 questions practice	Entire Body of Knowledge plus 300 questions practice
Certified Instructors (details will be provided if requested)	Srilata Thirunagari	Prabhakar Jain	Jack Reardon
Course Materials	Students are responsible for purchasing the materials (https://www.qualitycouncil.com) and also registering with ASQ (https://www.asq.org/cert) for the examination.		

Materials for all Courses:

Students must purchase their materials from the Quality Council of Indiana by calling 1-800-431-1585 and paying with a credit card once registration is confirmed. Materials to be purchased are as follows:

- Course Primer/ Books
- Electronic Exam for 1000 practice questions

Registration:

Registration will be confirmed after receipt of a check and registration information. The deadline for registration is Thursday, April 25, 2024. We need a minimum of 2 registrations to run the class. It is expected that students will become an ASQ member and take the next certification exam.

Please send an email to Raj Kasbekar at rkasbekar@gmail.com with the following information:

- Your name
- Email address
- Mobile phone number
- Mailing address

Raj will advise where to send a check.

THE APRIL 2024 SLT MEETING

The SLT met on April 9, 2024

- The section has ten new members in the April membership report
- The section’s website is updated
- An in-person section meeting on April 24 in Manchester, NH on Causal Loop Diagrams by Andy Moysenko



- A joint meeting with NH SME on May 22
- A joint on-line meeting on June 20 with the Worcester section on Medical Device Risk Management by Dan O’Leary
- The results of the Voice of the Customer survey
- The section has \$16,044.18 in its account

SLT MEMBERS NEEDED

The Section has some SLT positions to fill:

Arrangements Chair – Arrange the meeting facilities including venue, seating, room size, *etc.* Establish menu, negotiate fees, set up registration using Member Planet, provide the newsletter editor with the location and menu information. Arrange for the speaker equipment.

Treasurer – Keeps accurate section financial records, and reports to the SLT and to ASQ headquarters on financial matters.

Program Chair – Solicit speakers to match topics. Work with the Arrangements Chair to coordinate speaker needs. Work with the Newsletter Chair to publish events in a timely manner.

Database Chair – Download membership lists every month to ensure the section has the most recent member information. Assist the Section with use of member data for designated purposes.

Internet Liaison – Be available and knowledgeable of www.asq.org to answer questions and provide support to members who need assistance. Educate members on the features and information available on www.asq.org and encourage utilization of the section Web site.

The position descriptions are on the section website <https://www.asq104.org/nominations/position-descriptions>

If you are interested in one of these positions, please contact the Granite State Chair, Dan O’Leary, dan_judie@msn.com

SECTION METRICS

The Section is developing metrics to help measure success against the plans for the 2024 program year. The newsletter has a scorecard in Red/Yellow/Green format. A scorecard cell is white until the first scheduled activity.

Membership Change – Track the number of members for 2023 and 2024. Calculate the slope of the linear regression line. The target is a slope greater than zero and the improvement direction is up.

Meetings Held – The ratio of the number of membership meetings held YTD to the number planned YTD (at least four) expressed as a percentage. The target is 100% and the improvement direction is up.



Educational Events – The ratio of the number of educational events held YTD to the number planned YTD (at least one) expressed as a percentage. The target is 100% and the improvement direction is up.

Newsletters Published – The ratio of the number of newsletters published YTD to the number planned YTD (at least four) expressed as a percentage. The target is 100% and the improvement direction is up.

Member Surveys Conducted – The ratio of the number of member surveys conducted YTD to the number planned YTD (at least one) expressed as a percentage. The target is 100% and the improvement direction is up.

The scorecard cells are white until the first scheduled activity.

Metric	Target	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	NOV	DEC
Membership Change	Regression Slope ≥ 0	-0.07	-0.06	-0.05	-0.05							
Meetings Held	Percentage ≥ 100%		100%	300%								
Educational Events Held	Percentage ≥ 100%											
Newsletters Published	Percentage ≥ 100%	100%	100%	100%	100%							
Member Surveys Conducted	Percentage ≥ 100%			100%								

SECTION DEMOGRAPHICS

For April 2024, the section has 178 members with a wide geographical distribution and varied member types. For a map of member locations see the Granite State web site <https://www.asq104.org/membership>

State	Count	Percent
NH	149	83.7%
MA	14	7.9%
VT	8	4.5%
WI	3	1.7%
ME	2	1.1%
CT	1	0.6%
FL	1	0.6%
Total	178	100.0%

Member Type	Count	Percent
Professional Membership	134	75%
Senior Membership	35	20%
Retired Senior Membership	7	4%
Retired Professional Membership	1	1%
Student Membership	1	1%
Total	178	100%



VOICE OF THE CUSTOMER RESULTS

44 people opened the survey, 13 people clicked in, and 8 people responded.

What Type of Event Do You Prefer?

Event Type	Count	Percent
Live	4	50.0%
Remote	4	50.0%
Total	8	100.0%

What Type of Facility Do You Prefer?

Facility Type	Count	Percent
Restaurant	5	62.5%
Outside Venue	0	0.0%
Conference Center	2	25.0%
Other: remote	1	12.5%
Total	8	100.0%

What Event Format Do You Prefer?

Event Format	Count	Percent
Speaker Presentation	6	75.0%
Training	0	0.0%
Seminar	2	25.0%
Discussion	0	0.0%
Community Service Event	0	0.0%
Other	0	0.0%
Total	8	100.0%

Do You Want Tools For Your Career?

Want Tools	Count	Percent
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Yes	8	100.0%
No	0	0.0%
Total	8	100.0%

What Type of Tools?

Tool Type	Count	Percent
Business Plan Templates	0	0.0%
Problem Solving Templates	8	100.0%
Social Responsibility Templates	0	0.0%
Other	0	0.0%
Total	8	100.0%

What has the Section Done Well?

- The reoccurring time frame for the webinars is perfect! Between 1:00 and 2:00 EST. The content for most of them has been beneficial to my current position.
- Meetings with opportunity to earn RUs
- Held joint meetings with other sections to provide a variety of topics and opportunities for RUs
- attempted to contact all active members; begun working with neighboring ASQ Sections
- Presentations have been great
- Not familiar enough to make informed statement; not been an active participant enough to say

What Can the Section Do Better to Serve You?

- Some of the late night webinars (6:30-7:30pm) is too difficult for me to attend. It would be nice to see them offered during the day as well as at night. A first shift/second shift offering. Some webinars do not have enough time for their content.
- Conduct educational events.
- Restart education programs
- Presentations on Lean Six Sigma in non-manufacturing
- Please continue to offer events

CALL FOR SPEAKERS

Granite State members are invited to propose a presentation for an upcoming membership meeting. The presentations are about one hour following dinner. The topic should provide information about skills or knowledge useful in a quality professional's work. It should also relate to the Body of Knowledge of at least one ASQ certification. Express your interest in presenting to Dan O'Leary, dan_judie@msn.com.



In addition to recognition by other section members, a solid presentation can help refine your skills and may support your ASQ certification. Become a recognized subject matter expert!

CALL FOR AUTHORS

Granite State members are invited to write a Professional Development article for our newsletter. The content should provide information about skills or knowledge useful in a quality professional's work. It should also relate to the Body of Knowledge of at least one ASQ certification. A length of three pages or less would be best and may include figures and diagrams. Submit your draft article to Dan O'Leary, dan_judie@msn.com.

In addition to recognition by other section members, writing an article can refine your skills and may support your ASQ certification. Become a recognized subject matter expert and showcase your knowledge.

PROFESSIONAL DEVELOPMENT

Cost of Quality

Dan O'Leary CMDA, CQA, CQE, CRE, CSSBB

CQA: IV.B.3 Audit Program Management and Business Applications – Business and Financial Impact – Cost of quality (COQ) principles

Identify, describe, and analyze the audit program's effect on the four COQ categories: prevention, appraisal, internal failure, external failure. (Analyze)

CQE: II.E The Quality System – Cost of Quality (COQ)

Identify and apply COQ concepts, including cost categorization, data collection, reporting, and interpreting results. (Analyze)

Cost of Quality, COQ, is a financial method to help achieve an optimum balance in the allocation of resources related to non-conforming product. COQ uses financial information to help determine the optimum. Often the company's Chart of Accounts don't mesh with the COQ categories, which can raise difficulties with implementation.

COQ uses four cost categories as part of the analysis. They are:

Appraisal Costs – The costs incurred to determine the condition of a product, usually based on the “first time” appraisal.

Internal Failure Costs – The costs that would not be present if there were no nonconformances prior to shipment to the customer.

External Failure Costs – The costs that would not be present if there were no nonconformances after shipment to the customer.



Prevention Costs – The costs incurred to minimize the appraisal costs and the failure costs.

Determining these costs is not always easy from a traditional Chart of Accounts. For example, production operators may check product on the line. This is an Appraisal Cost, but is usually rolled up in the direct labor cost to produce the product. Similarly, maintaining an IM&TE calibration program is an Appraisal Cost, but might show up as an expense charged to the Quality Department.

Some examples of COQ elements are:

Appraisal Costs

- Incoming Inspection
- In-process Product Verification
- Final Product Verification

Internal Failure Costs

- Rework
- Repair
- Scrap
- Corrective Action Costs
- Machine Downtime

External Failure Costs

- Warranty Costs
- Returned Product
- RMA Processing Time

Prevention Costs

- Quality Planning
- Training Programs
- Preventive Action

A COQ program determines which costs to capture, the analysis method, actions based on the results, and management reporting.

The costs fall into the four categories, but the real action is in the cost breakdown. This means either collecting actual costs through the finance system or making good estimates.

Analysis typically falls into two parts. The first determines the comparison basis and the second determines the variance from the optimum point.

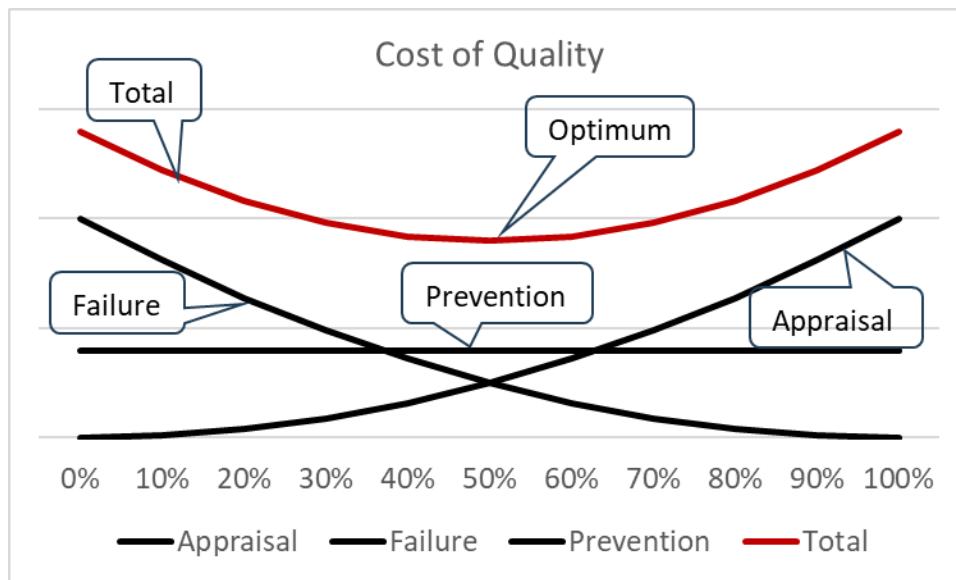


Express COQ as a percentage of some other relevant financial measure such as Sales Revenue or Cost of Goods Sold, COGS. Using a percentage is important to help compare over time and observe trends. For example, if sales are growing then the company will order more raw material which will increase the cost of incoming inspection, an appraisal cost. However, the incoming inspection cost should stay proportionate to the sales revenue. Similarly, if the field failure rate is constant then an increase in sales results in more failed devices increasing the external failure costs; the costs should stay proportionate to the sales revenue. An increase in quality costs with a proportionate increase in the base is normal; a nonproportionate change is of interest.

The optimum is a balance between the failure costs and the appraisal costs. The costs change as the nonconforming product rate changes and, at some point, achieve a minimum, the optimum point. See the figure below. The value of the minimum also includes the prevention cost, which is often fixed. For example, the cost of training on procedures is not usually a function of the product nonconformance rate.

When implementing COQ, one of the first steps is understand the optimum and where the firms is operating. This can help adjust the balance between the appraisal costs and the failure costs to move toward the optimum. For example, if the firm uses attribute lot sampling at incoming inspection, then implementing switching rules can reduce the appraisal costs without increasing the failure costs.

Reporting to management should include the percentage of cost of quality relative to the base. This suggests a trend chart for reporting. At each reporting interval, expect a downward trend, but there will be variability. Some periods will show an increase, so the overall downward trend is important, not so much the value at each individual period.





QUALITY QUESTION

This area of the newsletter responds to quality questions from Granite State members. The question could be about best practices, implementing a method, using a statistical technique, *etc.* Submit your quality question to Dan O’Leary, dan_judie@msn.com.

Question: When referring to a standard in a procedure or work instruction should we include the revision year? We make medical devices and have many references to ISO 13485. Should we refer to ISO 13485:2016 by adding the year of the current revision? I see the benefit in either argument, I just want to find out the best practice for something like this.

Response: While the question relates to medical device standards, the issue cuts across all industries.

There are two conventions. Without the revision, you are referring to a generic version. For example, "ISO 13485 provides requirements for a medical device QMS".

More often you are referring to a specific version. If your procedures refer to the standard, it should be the specific version, which is ISO 13485:2016, since it includes the requirements you are following.

If you market your device in the EU, then your QMS must follow the EU requirements in EN ISO 13485:2016/A11:2021. You need to be clear about whether your QMS implements the international version or the EU version.

In most cases, it is best if the procedure does not refer to the standard. The procedures should tell the people involved how to perform the associated process. The reference to the standard doesn't usually add value or improve the effectiveness of the procedure. It only creates a need for massive revisions when the standard changes.

A more efficient approach is to refer to the standards in some master document, such as the Quality Manual. This identifies the specific versions in your QMS, but it doesn't require you to update lots of procedures when a standard is revised.