Energy & Environmental Division
ASQ The Global Voice of Quality®

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ENERGY & ENVIRONMENTAL DIVISION NEWSLETTER

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Chair's Message | Greg Allen

Keeping the Pace

If the Energy and Environmental Division *keeps its pace, 2017 will be a great year! We are creating new products, such as a revision of the* Nuclear Quality Auditor Handbook*. We are expanding the member leader workforce, including identification of a division affairs coordinator for the ASQ Middle East and Africa (MEA) region.*

Division council members are leading an effort to refresh the body of knowledge to ensure only current information is provided to division members. Our communications are getting more regular, including re-establishing frequent newsletters. The division has direct involvement in standards bodies such as the U.S. Technical Advisory Group for the ISO 14000 family of environmental standards. We are expanding division activity into emerging areas where quality is essential, such as in the field of energy management systems.

There are limitless opportunities for division members to participate. Whether you are a quality professional who currently works in energy or environmental fields, or you are considering a career shift, your professional success and personal satisfaction can be enhanced by being part of the action in the Energy and Environmental Division. Visit our website at asq.org/ee/about/leadership-ee.html and contact me or a member of the division council to identify opportunities to be involved. Let's stay on a roll in 2017!

Greg Allen
Chair, ASQ Energy and Environmental Division

CPR for Internal Auditing of Management Systems

Continuing to conduct internal audits for management systems assessments in the same manner as we have always done in the past is inviting your registration auditor to write a major nonconformance against your management system! Your internal auditors will need to learn some new techniques, which can be easily remembered as CPR—conformance, process approach, and risk.

The abbreviation is intended to remind auditors what they should be doing to conduct internal first-party audits for their organizations. With the release of the ISO 9001:2015 quality management system (QMS) and the ISO 14001:2015 environmental management system (EMS), internal auditors are required to do much more when conducting conformance audits.

Organizations registered to these management systems are required in EMS 4.4.2 and QMS 6.2.2 to ensure employee competence training (which will include internal auditor training) and associated records if an employee's work impacts the environment or may affect quality (auditors can affect both the environment and quality of product). With the standards full of references to risk, risk-based thinking, and identification of system effectiveness—which connotes the concept of the process approach—this is seen as the basis for the new requirements that your internal auditors will need to meet.

About four years ago, I joined one of the large registrars as a full-time lead auditor. The wide exposure to a greater number of organizations around the United States was a surprise to me in that 80 to 85 percent of the clients were still only conducting

Author

Dr. Roderick A. Munro, ASQ Fellow, CMQ/OE, CQE, CQA

"conformance" internal audits (which manifest themselves by the company only auditing to the clauses of the standard instead of across the process for the process approach, which should have started in ISO 9001:2000). A number of other full-time lead auditors at numerous other registrars confirmed the observation. It seems that the non-industry specific QMS organizations (e.g., aerospace, automotive, and others) across North America did not update their internal audit programs back in 2000. This was probably due to the words "process approach" not being aligned to a "shall" statement in both the 2000 and 2008 versions of the ISO 9001.

Conformance auditing to the clauses was the basic foundation of management systems audits that began in 1988 when companies used, "Say what you do; do what you say," and used the internal audit to "prove it." These management systems audits have now expanded into other specific areas (e.g., environment, safety, asset management, energy management, and a number of others). This new approach to management systems emphasizes conformity with the requirements of the governing standards. The general tipoff that an internal audit program is primarily conformance based is the sole use of checklists to complete the audits. Copies of procedures, work instructions, and other documents observed during the internal audit are sometimes found with the reports or auditor notes to provide evidence the auditor reviewed the area in question and personnel are following the company-identified procedures. This evidence is still needed, as seen in both the 2015 versions of ISO 9001 and ISO 14001: 9.2.1 a), which asks to show conformance; however, will not suffice to meet the new requirement 9.2.1 b), which states "effectively implemented and maintained" is now required. Note: under the ISO Annex SL a new ammonized structure exists with elements 4, 5, 6, 7, 9, and 10 meant to be similar. In fact, both ISO 9001 and ISO 14001 contain common statements for internal audits in element 9.2. Also note that ISO 19011:2011 states in 7.1 Competence and evaluation of auditors – General, that: *Confidence in the audit process and the ability to achieve its objectives depends on the competence of those individuals who are involved in planning and conducting audits, including auditors and audit team leaders.* This standard clause lays out the general criteria for evaluating the competence of the auditors to conduct audits on your entire management system.

So What Is Process Approach?

The ISO 9000:2015 (the ISO document that contains the terms and definitions for ISO 9001:2015) states in 2.3.4.1, *"Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes as a coherent system."* An organization is made up of many interrelated processes and methods that combined together will produce a product or service for a customer. Since ISO started the management system series in 1988, internal auditors were only required to verify the various departments in the company were following the prescribed procedures (conformance auditing). As stated earlier, the concept of the process approach was first addressed in the foreword of ISO 9001:2000, with many clever consultants (C²s) highlighting that since there was no "shall" associated with conducting the process approach, auditors could continue to only conduct conformance audits to the standard clauses.

ISO 9001:2008 did use the term "effectiveness" 15 times, but few people seemed to have made the tie-in with the concept of "process approach." In the 2015 standards, ISO 9001 uses the term "effectiveness" 17 times, and ISO 14001 uses "effectiveness" 11 times.

In ISO 9001:2015, some of the same C²s are trying to push clients away from conducting internal audits using the process approach and/or risk-based thinking (trying to argue incorrectly that the standards do not require auditors to audit these aspects)! However, with the statements in ISO 9001:2015 in 5.1.1 d) that managers "shall" demonstrate leadership in the promotion of both process approach and risk-based thinking and the unstated fact that internal audits should be a key tool of the leadership team, then a *de facto* process has been established. Also, 9.2.1 b) states the internal audit "*shall be: effectively implemented and maintained*." How do you have an effective internal audit process if you are not utilizing the underlying process approach and risk to evaluate the system?

To put this simply—in terms of what the internal auditor needs to do in addition to conformance activities (following their checklists)—internal auditors need to create a flowchart of each area that they review during the audit! There are many other tools that could be used (e.g., turtle diagrams, SWOT analysis, spaghetti diagrams, etc.), but the point is to look at the overall flow of the area to see if it makes sense and to look for areas that could potentially be improved. Thus, the internal auditors are reviewing the "effectiveness" of the system. This change to the internal audit process is one step toward moving from the old concept of quality control to a more proactive approach using quality assurance methodologies. This is why we include the "P" for process approach as the second letter in the acronym.

The third factor of CPR is for the risk factor or risk-based thinking. There are multiple ways the internal auditor can question fellow employees about things that could go wrong in the work setting. One key to remember is that "Murphy was an optimist." It is not necessarily the role of the internal auditor to evaluate what the risk levels are. That should be left up to management. The internal auditor should be concerned with collecting any number of potential risk or opportunity statements and reporting them in their findings. Thus, for the internal auditor, the key is to ask everyone what could go wrong in each respective area of the site as they talk with everyone in the organization.

As for the term "risk," ISO 9001 uses the direct term nine times, while ISO 14001 uses the direct term seven times. We say "direct term" here as Mark Ames, a U.S. TAG 176 member for many years, pointed out in an ASQ webinar in 2015, that whenever the words "suitable" or "appropriate" are used in the standard, the intent was to be around risk-based thinking (I wish they had just used the word "risk" to prevent confusion). With this thought then, the term "risk-based thinking" is used 34 times for ISO 9001 and 22 times for ISO 14001.

With this new requirement for risk-based thinking, it will probably make sense to develop a new procedure around how to cover this material for risk-based thinking. Many of the C^2s are pushing any number of tools to analyze risk (utilizing timeframes, impacts, consequence, priority, ranking, cost, or other factors). The key point here—and given that this is a totally new requirement—is to keep it simple, stupid (the KISS principle)! Either a three-step (high/medium/low) or a five-step (critical/high/medium/low/ignore) approach is appropriate depending on what your organization is already using in either your environment or safety programs. Since we want one overall management system, if you already have a risk assessment process in place, use that same process for the entire system. So, a word to the quality professionals is to go talk to the safety and environmental groups.

CPR for Internal Auditors

If your internal audit team has not previously been trained in the process approach, they need to be trained quickly. *If I were a quality manager or top leader in an organization today, I would have already updated the training for my team as well as offered some form of briefing for managers on how to utilize the internal audit process to help improve the organization beyond just conformity.* In addition, internal auditors, managers, and supervisors need to learn and utilize risk-based thinking to help ensure that the interrelationships within the organization are effective in meeting the customer's wants and needs.

With most organizations not yet having transitioned to ISO 9001:2015 or ISO 14001:2015, it is imperative that your organization start moving as quickly as possible in utilizing CPR in your internal auditing process. It will take time for people to practice using the new techniques of process approach auditing and risked-based thinking without it developing into advanced tool as a failure mode and effects analysis (FMEA). We are not to the point, at least yet, of having to create a management system FMEA.

EED Perspectives on the Current Nuclear Climate

The ASQ Energy and Environmental Division Nuclear Committee evaluates the quality, safety, and risk elements of nuclear activities to apply standards and protocols that ensure best practices are employed in the nuclear industry, supplier organizations, and related partners. EED Nuclear Committee members represent nuclear utilities and suppliers, architect/engineering firms, federal government agencies, national laboratories, management and operating contractors, and private consultants.

Nuclear power remains the primary baseload clean energy source providing ~20 percent of domestic power, and operating at 90 percent capacity with no greenhouse gas emissions—this encompasses 60 percent of the United States' noncarbon-emitting energy portfolio. However, nuclear energy has not been provided with incentives available to other clean energy sources—low carbon/zero emission subsidies would optimize clean power sources. Low domestic natural gas prices have served as a disincentive to nuclear power, with resultant impacts including scheduled decommissioning of seven domestic nuclear reactors, recent closure of 14 nuclear reactors with nine scheduled for closure (including those prematurely closed during initial 40 years of operation). This adverse impact to clean nuclear power is solely due to rate structure/economic issues and has resulted in increased domestic carbon emissions.

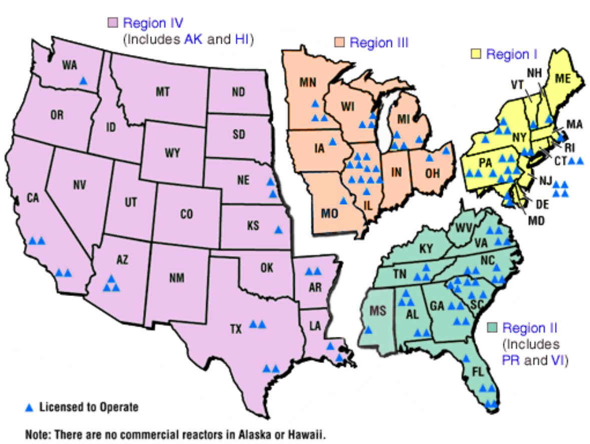


Figure 1
Domestic Nuclear Power Reactors – January 2017
Source: www.nrc.gov.

There are currently 99 commercial operating nuclear reactors (Figure 1, U.S. NRC) in the continental United States and 449 international reactors located in 30 countries as depicted in Figures 2 and 3 (IAEA). Following rigorous safety review of applications, the original NRC license authorizing the 40-year design lifetime for domestic light water reactors has been extended to

Author

Karen Douglas, EED Nuclear Committee Chair

60 years (85 units approved, 13 units pending) with two utility applications for 80-year subsequent license renewals (Peach Bottom Units 2 and 3, 2018; Surry Units 1 and 2, 2019).

New light water power reactor initiation domestically includes 18 NRC combined construction and operating license applications (30 units), with five COL granted in 2015, and construction of four units underway. Internationally, 66 new reactors were under construction in 2015, with 40 percent of new units Russian-sponsored (Russia has committed to building new reactors in China, Hungary, India, and Turkey, with

Figure 2
International Nuclear Power Reactors – January 2017

Current Status:

449 NUCLEAR POWER REACTORS IN OPERATION

392,193 MW_e TOTAL NET INSTALLED CAPACITY

2 NUCLEAR POWER REACTORS IN LONG-TERM SHUTDOWN

60 NUCLEAR POWER REACTORS UNDER CONSTRUCTION

17,003 REACTOR—YEARS OF OPERATION

Source: www.iaea.org.

Regional Distribution of Nuclear Power Plants

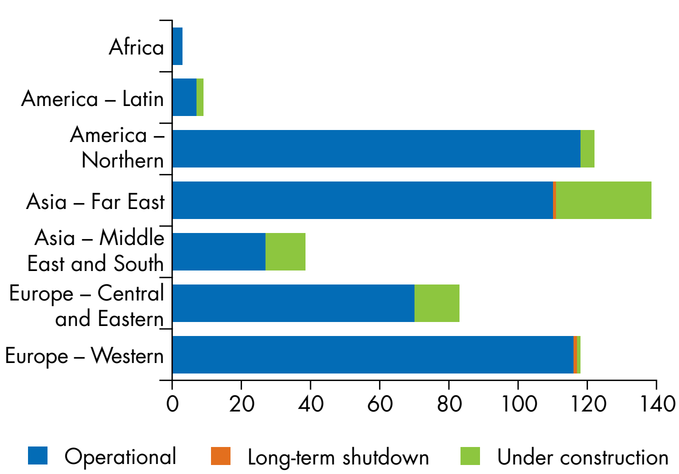


Figure 3
Nuclear Power Reactors (by Country) – January 2017

The total number of reactors also includes six reactors in Taiwan, China.

Country	Number of reactors	Total net electrical capacity [MW]
ARGENTINA	3	1,632
ARMENIA	1	375
BELGIUM	7	5,913
BRAZIL	2	1,884
BULGARIA	2	1,926
CANADA	19	13,524
CHINA	37	32,402
CZECH REPUBLIC	6	3,930
FINLAND	4	2,752
FRANCE	58	63,130
GERMANY	8	10,799
HUNGARY	4	1,889
INDIA	22	6,225
IRAN, ISLAMIC REPUBLIC OF	1	915
JAPAN	42	39,752
KOREA, REPUBLIC OF	25	23,125
MEXICO	2	1,552
NETHERLANDS	1	482
PAKISTAN	4	1,005
ROMANIA	2	1,300
RUSSIA	35	26,172
SLOVAKIA	4	1,814
SLOVENIA	1	688
SOUTH AFRICA	2	1,860
SPAIN	7	7,121
SWEDEN	10	9,748
SWITZERLAND	5	3,333
UKRAINE	15	13,107
UNITED KINGDOM	15	8,918
UNITED STATES OF AMERICA	99	99,868
Total	**449**	**392,193**

Source: www.iaea.org.

potential buyers in Jordan, Kazakhstan, Nigeria, South Africa, and Vietnam) and 24 reactor construction sites in China.

Additional disincentives to more widespread adoption of nuclear power as a preferred clean energy source include lengthy/expensive nuclear reactor licensing, construction costs, and repository siting; interim storage of spent nuclear fuel; and disposal of resultant radioactive wastes (first international spent nuclear fuel repository—2016 Finland construction license).

The ASQ EED Nuclear Committee strives to ensure factual representation of nuclear power to the public and application of adequate controls to ensure safety of workers and the public. Current and projected ASQ EED Nuclear Committee activities and contributions include:

- Preparation of *EED Nuclear Quality Assurance Auditor Training Handbook* (previously *Quality Systems Auditor Training Handbook*)
- Potential revision of ASQ EED International Matrix of Nuclear QA Requirements (1995)
- Collaboration with nuclear industry organizations, standards organizations, and professional societies to promote responsible application of nuclear power (e.g., IAEA, NEI, EPRI, INPO, ANS, ASME, IAEA, NEI, INPO, EPRI, EFCOG, NUPIC, American Energy Association, Clean Energy Business Council)
- ASQ coordination with ASME for ASME NQA-1 "Quality Assurance Requirements for Nuclear Facility Applications"
- Production of ASQ webinars, EED newsletter articles, conference and section meeting presentations offering value to ASQ membership
- Involvement with safety and quality assurance of independent spent fuel storage installations and nuclear decontamination and decommissioning efforts

These nuclear quality-related issues will be covered in greater detail in subsequent newsletters and information-sharing activities. Please consider additional contributions the ASQ Energy and Environmental Division can offer to promote safe, responsible generation of energy to the consumer while minimizing costs and impact to the environment.

Note: This report is provided for informational and educational purposes. The views expressed are those of the author and not necessarily those of the National Nuclear Security Administration (NNSA) or the U.S. government.

ASQ MEA Head | Kavitha Prabhu

Key Initiatives by ASQ Middle East and Africa (MEA)

ASQ Middle East and Africa (ASQ MEA) www.asqmea.org has seen recent success by launching the ASQ MEA Regional Quality Conference in the United Arab Emirates (UAE) in 2015. Since then the conference has been an annual event attended by a large number of quality professionals to share best practices, expand their network, and further develop their professional growth. Here is a link to the 2016 conference with photos: www.asqmea.org/regionalqualityconference.php.

Also in 2015, ASQ MEA established the ASQ UAE Quality Professionals Award. The award is the first of its kind in the Middle East. An award like no other in the region specifically introduced for quality, continuous improvement, and performance excellence professionals outside of the Americas. For the third year, ASQ MEA strives to make this award an engaging journey for all quality professionals who want to pursue their quest for excellence and make a sustainable impact on businesses and communities in the UAE. The award cycle for 2017 is open and can be found at www.asquae-award.org.

Last year, in pursuit of empowering students to improve quality and its use in the local environment, ASQ MEA launched the Student Case Study Competition, which was well received with a large number of students participating. ASQ MEA will organize its second phase during the 2017 conference in Dubai. With the objectives to educate, engage, connect, and inspire leading professionals from around the globe, the conference, the ASQ UAE Quality Professionals Awards, and the Student Case Study Competition are opportunities for quality professionals to be recognized for their achievements, efforts, and contribution to quality improvement in the region.

Another regular initiative undertaken as a member benefit through local member communities is the opportunity for site visits to organizations that are practicing quality improvement standards. Members have seen huge value through these visits and meetings, as it serves to be an excellent platform for learning best practices and industry standards.

Recently, through collaborative partnership with ASQ MEA, the region provides many opportunities for specialized divisions to provide training to overcome skill gaps in the region. This October, ASQ, in collaboration with the ASQ Reliability Division, will organize training for ASQ MEA 2017 Regional Quality Conference attendees. Similarly, ASQ and the EED plan to strengthen ties through a strategic partnership. ASQ MEA will look to promote workshops, seminars, and training supported by EED with subject matter experts and speakers. ASQ MEA recognizes the needs of EED members in the region and is willing to support the energy and environmental initiatives of the EED.

ASQ EED Nuclear Committee 2016-2017

Karen Douglas,
Nuclear Committee Chair

Dr. Greg Allen,
EED Chair

Irene Michelle Dudley

Mike Gilman

Jim Hill

Bob Mitchell Ivey

Ben Marguglio

Greg Merkel

Chuck Mosely

Tom Mudge

Harikumar Nayak

Tom Niessen

Samuel Reddy

Dr. Abhijit Sengupta

Benjamin Trujillo,
DCD Chair

Jeffrey Worthington

ASQ China Head | Fred Zhang

Status of ASQ North Asia

During 2016, ASQ North Asia provided excellent service for members and clients. ASQ branding and awareness expanded through social media, conferences/workshops, and e-marketing.

ASQ North Asia now has an official Wechat account (*ASQ_China*) and Sina Weibo account (*ASQ_China*) for ASQ news, events, training, and local member community (LMC) activities. ASQ North Asia followers can chat online. It is now much more convenient for members to get the latest information on ASQ and quality. Each year, ASQ North Asia will select two to three hot quality-related topics and compile a local magazine translated from the ASQ flagship magazine—*Quality Progress*. ASQ North Asia also has developed an ISO 9001:2015 and a risk management magazine, and the work continues.

ASQ North Asia continues good relationships with the local government bureau and local association for quality. ASQ North Asia participates in the most important quality conferences in China either as speaker, co-host, or sponsor/endorser. Last year, ASQ North Asia co-hosted two workshops on the 2016 ASQ Global State of Quality Research to share with quality professionals in Shanghai and Shenzhen. ASQ North Asia also sent speakers to the 2016 China Quality Expo and 2016 China International Food Safety and Quality Conference and Expo to expand ASQ awareness.

The local member community (LMC) plays an important role for our members. ASQ North Asia now has five LMCs in North Asia, including Shanghai, Beijing, Shenzhen, Hong Kong, and Taiwan. The monthly LMC events provide members opportunities to learn and communicate with quality experts and professionals. Quality-related hot topics, tools, methods, and best practice are discussed at these events.

In addition to ASQ certification-related training courses, ASQ North Asia continues to develop new training courses for local members. Training courses cover such subjects as Baldrige, innovation, ISO 9001:2015 implementation, and quality leadership through e-learning courses in the local language, and are directed at providing the entire suite of quality training needs.

In August 2017, ASQ North Asia will host the 1st Great China Conference on Quality and Improvement (GCCQI) in Shanghai. The conference theme is: *Economics and the Future of Quality*. Conference focus areas include:

- New Technologies: Challenges of Quality in Intelligent Manufacturing Era
- New Horizon: Quality Management in Emerging Industries
- New Value: The Whole Value Chain Excellence Through Quality Management
- New Levels: Performance Excellence and Best Practice

Quality experts and top management will be invited to share their experiences and knowledge at the conference. GCCQI is a great platform for the local members and quality professionals to get connected with the quality community, get engaged in the dialogue with top management, and get inspired by best practice!

Visit http://e.eqxiu.com/s/ewt62x9L?eqrcode=1 for more details!

ASQ RD Coordinator for Regional Councilors | Dan Burrows

ASQ Reliability Division: Who We Are and How We Can Help

Part 1

If your organization is involved in design, production, or quality, then reliability is probably important to you. You probably know your customers want a reliable product, but you may not know how to achieve high reliability. The ASQ Reliability Division (RD) can help!

The ASQ RD is the largest group in the world that promotes reliability training and education (www.asqrd.org). In addition, the Reliability Body of Knowledge (BoK) is our foundation.

The ASQ Reliability Division offers:

- Training courses
  - On-site at conferences or as stand-alone (we often partner with ASQ sections)
  - Live webinar training (upcoming webinars)
  - A library of 160+ webinars for members (past webinars)
  - All with the ability to earn certificates for proof of training (and ASQ recertification units)
- Conferences
  - Sponsor for RAMS (www.rams.org) Reliability and Maintainability Symposium—the world's largest reliability conference
  - Sponsor for ASTR (www.ieee-astr.org) Accelerated Stress Testing and Reliability—focused accelerated testing
- Regional councilors are a part of our front-line engagement with ASQ sections and other professional and public organizations.

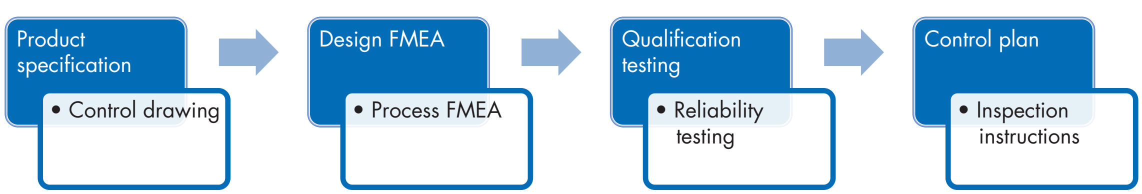
So, what is reliability? ***Reliability*** is the probability that an item will perform its intended function for a specified interval under stated conditions following prescribed procedures. What that really means:

- You must know the customer's needs.
- You must know the application and usage.
- You must know the expected usage life.
- You must know how to maintain reliability.

It means, "***quality over time***."

We work with quality through structured processes like: failure mode and effects analysis (FMEA), fault tree analysis, failure reporting and corrective action (FRACAS), and a number of others.

Quality and reliability start from the requirements and flow to design, testing, and production:



EED Participates in ASQ's South Asia Conference

Debashis Sarkar, ASQ Fellow, Phil Crosby Medalist, Managing Partner, Proliferator Advisory & Consulting

ASQ's first South Asia Conference on Quality and Improvement, with the theme "Manifesting Intent Through Execution," was held on December 16 – 17, 2016, at the Vivanta by Taj hotel in Dwarka, New Delhi, India. More than 200 quality professionals attended the conference. A total of 38 speakers from across the country provided technical presentations, including India's union minister of railways who addressed the conference via video.

Conference photos

The conference also was attended by Bill Troy, ASQ CEO; Andrew Baines, managing director, ASQ Global; Denis Devos, Quality Management Division (QMD) vice chair global; and Kush Shah, ASQ board member.

The conference was co-sponsored by the ASQ QMD.

Topics covered at the conference included:

- Leadership for Strategic Quality Execution
- Making Execution Easy
- The Road from Intent to Execution
- Leading for Excellence and Sustainable Growth
- Leadership Lessons Beyond Business
- How Disruptive Innovations Shall Alter Our World
- Using Technology, Innovation, and Quality to Delight Customers
- Engineering Exemplary Customer Experiences
- Innovating Exemplary Customer Experiences

I represented EED at the conference and shared a booth with the QMD. All attendees who visited the booth received a division brochure and discovered the benefits of becoming a member. There were many questions about EED membership and how it can benefit one's career.

Overview of Nuclear Quality Standard NQA-1

The Nuclear Quality Assurance consensus standard, NQA-1, is published by the American Society of Mechanical Engineers (ASME). The standard is supported by a committee of industry volunteers who report to the ASME board of nuclear codes and standards. The standard was developed under procedures accredited as meeting the criteria for American National Standards (ANS). The standard reflects industry experience and current understanding of the QA requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy by focusing on the achievement of results, emphasizing the role of the individual and management, and applying the requirements in a manner consistent with the relative importance of the item to safety.

The initial standard issued was American National Standards Institute (ANSI)/American Society for Mechanical Engineer (ASME) N45.2, 1977. The document was supported by 14 Daughter Standards each describing a specific area of quality assurance, for example: N45.2.6 (Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants), N45.2.9 (Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants); and N45.2.11 (Quality Assurance Requirements for the Design of Nuclear Power Plants).

Early in 1975, ANSI assigned overall responsibility for coordination among technical societies, development, and maintenance of nuclear power quality assurance standards ASME.

NQA-1-1979 was first published in 1979, with the edition being the year of publication. The version consolidated seven N45.2 criteria into NQA-1-1979 and consolidated seven N45.2 work

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EED Membership

practices, i.e., cleaning, packaging, storage, housekeeping, etc., into NQA-2-1979.

NQA was revised and published in 1983, 1986, 1989, 1994, 1997, 2000, 2004, 2008, and 2015. Addenda for changes and additions may be issued yearly and are shown as a small letter after the volume, i.e., NQA-1a-1999.

The 1994 edition combined the NQA-1 and NQA-2 documents into a single document to improve readability. NQA-1-1994 was significantly rewritten to combine basic and supplements into a part to remove unnecessary boilerplate, clean up language (clarity and consistency), separate Nonmandatory Guidance into Part III – Applications, and add Part IV for Matrices and White Papers.

NQA-1-1997 was a major revision reflecting proven philosophies and providing a performance-based standard: Some detailed requirements, primarily from Daughter Standards, moved to Non-mandatory Guidance. Main features were performance-based/results-based requirements retained, sharpened focus on management's role in achieving quality, graded application clearly embraced, deleted redundancy, and specified criteria applicable to all applications.

Federal Regulation, 10 CFR 50, Appendix B - *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants* issued in 1970 (revised 1975) requires every applicant for a construction permit to provide a description of the QA program to be applied to the design, fabrication, construction, and testing of the facility. The Regulations Invoking QA Requirements: 10 CFR Part 50, *Domestic Licensing of Production and Utilization Facilities* Part 50.34, "Contents of Applications," and Appendix A, Criterion 1, require a quality assurance program in accordance with Part 50, Appendix B.

NQA-1 Structure has 4 parts.

- Part 1 Requirements encompasses 10 CFR 50 Appendix B criteria.
- Part 2 Applications includes the content of the NQA-2 Standard.
- Part 3 Non-mandatory Appendices provides acceptable method of compliance.
- Part 4 Positions and Application Matrices

Part 1 of NQA-1 has 18 criteria: 1) Organization, 2) Quality Assurance Program, 3) Design Control, 4) Procurement Document Control, 5) Instructions, Procedures, and Drawings, 6) Document Control, 7) Control of Purchased Items and Services, 8) Identification and Control of Items, 9) Control of Special Processes, 10) Inspection, 11) Test Control, 12) Control of Measuring and Test Equipment, 13) Handling, Storage, and Shipping, 14) Inspection, Test, and Operating Status, 15) Control of Nonconforming Items, 16) Corrective Action, 17) Quality Assurance Records, and 18) Audits.

Part 2 Applications deal with Cleaning of Fluid Systems, Packaging, Shipping, Receiving, Storage and Handling, Housekeeping, Instrumentation, Concrete, Steel, Soils and Foundations, Computer Software, Mechanical Equipment and Systems, Hoisting, Rigging, and Transporting, Maintenance, Subsurface Investigation, Decommissioning.

Part 3 Guidance works with Organization, Qualification of Inspection Personnel, Qualification of Auditors, Surveillance, Design Control, Procurement Document Control, Control of Purchased Items and Materials, Commercial Grade Items, Inspection, Test Controls, Corrective Action, Quality Assurance Records, and Audits.

Part 4 Covers Software Applications, Graded Application of QA for Nuclear-Related, Research and Development, Documents under development include:

Current NQA-1 Standard users are US Nuclear Power Industry, ASME Boiler and Pressure Vessel Code Organizations, ASME Code Material Suppliers, National Labs and DOE Contractors, Nuclear Utilities Procurement Issues Committee (NUPIC) Audits, Dry Cask Storage User Group Audits, Westinghouse Electric Company (NSSS), Westinghouse Savannah River, Yucca Mountain Project, Waste Isolation Pilot Plant (WIPP), Non-Nuclear Users (i.e., Alaskan Pipe Line)

ASME NQA-1 is a mature, current standard that is recognized and utilized worldwide based on its proven ability to achieve results consistent with existing CFRs applicable to the complete life cycle supported by a responsive committee of industry volunteers and ASME's world-class organization.

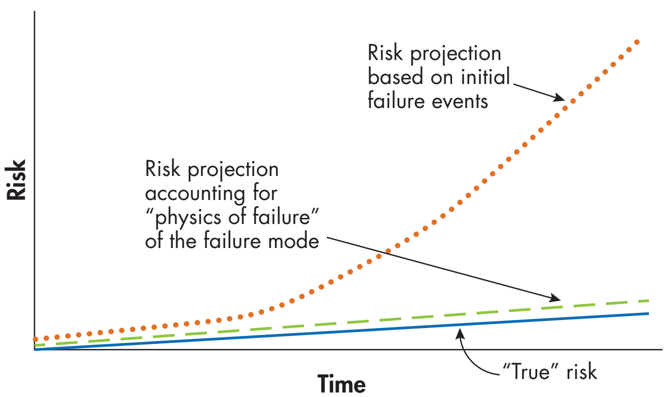
Note: This report is provided for informational and educational purposes. The views expressed are those of the author and not necessarily those of the U.S. government.

Using Weibull Analysis in Probabilistic Risk Assessment

Probabilistic risk assessment is used to predict future risk—both number of future events and the event rate.

Probabilistic risk assessment is a decision-making tool that helps management determine appropriate risk management actions. However, in order to be of value, probabilistic risk assessment requires the definition of **acceptable risk thresholds**.

First, the steps in a probabilistic risk assessment are:



Understanding the Physics of Failure Is Important for Successful Risk Predictions

- Understand cause of failure/type of failure mode
- Define population at risk
- Define historical data
- Use the event prediction method: Weibull/lognormal distribution(s), usually in conjunction with Monte Carlo simulation—especially in complex system problems
- Determine severity factor (probability of basic event leading to a safety event)
- Compare calculated risk to accepted threshold values
- Determine appropriate risk mitigation actions

Risk Assessment Example

- Component in automobile system has fracture failure mode with potential safety hazard
- LCF crack initiation Weibull: $\beta = 1.8$, $\eta = 300{,}000$ miles
- Crack propagation Weibull: $\beta = 3.3$, $\eta = 10{,}000$ miles
- Fracture time = crack initiation time + crack propagation time

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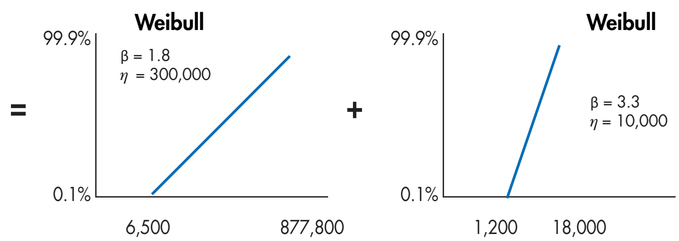
- Historically, there have been three fractures, the last one nearly caused a catastrophic failure
- Inspection probability of detection: 0.98
- New fleet of 1,000 automobiles, average 25,000 miles/year used for 10 years
- Acceptable risk threshold: No more than 0.7 catastrophic failures in fleet usage
- Is risk acceptable? Are additional risk mitigation actions needed?

Risk Calculation Steps

1. **Understand the failure mode**
    - Fatigue failure mode represented by wear-out Weibull distribution
2. **Population at risk**
    - 1,000 new automobiles
    - Utilized for 10 years at 25,000 miles/year
    - Per automobile: 1 unit × 10 years × 25,000 miles/year = 250,000 miles
    - Fleet: 1,000 units × 10 years × 25,000 miles/year = 250,000,000 miles
3. **Historical data**
    - Three previous fracture events:
        - Two found during shop maintenance
        - One found by the operator seeing smoke
    - Historical events/lab findings used to generate crack initiation and crack propagation Weibull distributions
4. **Prediction method**
    - **Time to fracture = Time to crack initiation + Time to crack propagation**



Note: Using Monte Carlo Simulation Is a Quick Method to Combine the Two Distributions

Monte Carlo Simulation to Obtain Fracture Time Distribution (using Excel)

β = 1.8 3.3
η = 300,000 10,000

Rand-1	Rand-2	CrkInt	CrkPrp	Fracture
0.118656	0.965667	95042	14453	109495
0.118656	0.965667	95042	14453	109495
0.405042	0.877834	208451	12525	220976
0.390942	0.644642	203174	10104	213277
0.241981	0.661275	147038	10243	157281
0.40965	0.725364	210179	10808	220987
0.85696	0.442366	434096	8496	442593
0.596606	0.349101	284311	7740	292051
0.105747	0 .31428	88798	7442	96241
0.190374	0.745872	125454	11001	137455
0.96118	0.870937	577317	12425	589742
0.37257	0.980895	196316	15172	211488
0.897732	0.177374	474232	6096	480328
0.981597	0.937834	647609	13629	661238
0.567736	0.867214	272073	12373	284446
0.845851	0.444288	424740	8511	433251
0.049318	0.522813	57159	9127	66287
0.267342	0.946379	156813	13845	170657
0.448225	0.995514	224749	16676	241425
0.68688	0.63802	325957	10049	336016
0.134129	0.821131	102230	11788	114018
0.0618	0.451979	65028	8572	73601
0.393323	0.387555	204064	8057	212121
0.988678	0.818232	690232	11755	701987
0.778191	0.010743	376620	2536	379156
0.100314	0.595149	86092	9708	95800
0.935606	0.574694	525481	9536	535017
0.770592	0.086947	371916	4836	376752

Random numbers

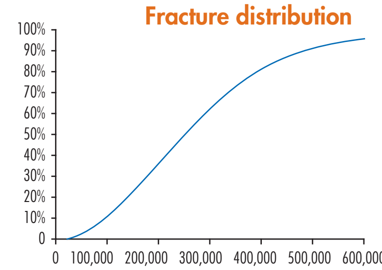
Calculated times initiation, propagation, fracture

Sorted Fracture	Cum Pct
10860	0.05%
15439	0.10%
16459	0.15%
19771	0.20%
22145	0.25%
23259	0.30%
24886	0.35%
26177	0.40%
26714	0.45%
27628	0.50%
30569	0.55%
31351	0.60%
31677	0.65%
33369	0.70%
33411	0.75%
33593	0.80%
35308	0.85%
35476	0.90%
35541	0.95%
35647	1.00%
35660	1.05%
35890	1.10%
36089	1.15%
36566	1.20%
37553	1.25%
38026	1.30%
38881	1.35%

Fracture time sorted

Cumulative percentage calculated

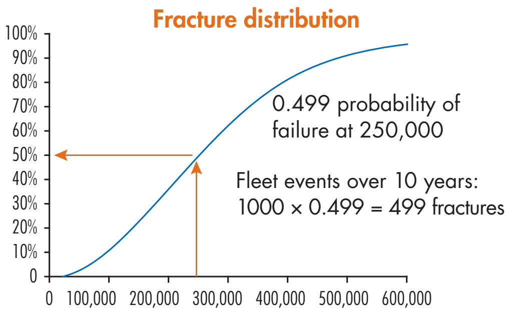
Fracture distribution



5. **Severity factor: three historical events, one nearly catastrophic … SF = 1/3 = 0.333**

6. **Calculate risk, compare to threshold**

   Each automobile accrues 250,000 miles over 10 years



- 499 fractures predicted in fleet of 1,000 automobiles over 10 years
- 499 fractures × 0.333 catastrophic events/fracture = 166 catastrophic events
- Acceptable threshold = 0.7 catastrophic events in fleet

Risk is unacceptable … corrective actions required.

7. **Appropriate corrective actions**

   Several options can be considered to reduce risk:

   a. Replace component at a defined limit

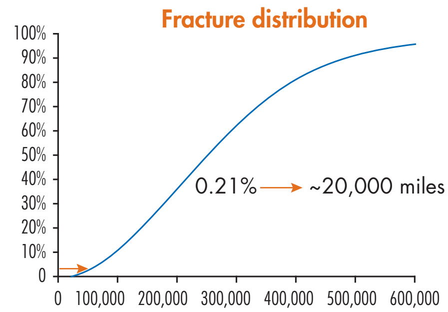
   b. Inspect component at defined frequency

   c. Retire automobile fleet early

   d. Redesign component to eliminate failure mode

Continuing,

1. Acceptable threshold criteria = 0.7 catastrophic events in fleet
2. 0.333 is severity factor, or probability of a fracture leading to catastrophic event
3. This translates to 0.7 catastrophic events/0.333 = 2.1 fractures acceptable
4. Each automobile cannot exceed 2.1/1,000 = 0.0021 fractures



Indicates life limit will be restrictive and costly … evaluate other options

Next Possible Step: Recurring Inspections Are a Common Risk Mitigation Action

- Inspection effectiveness is a function of probability of detection (PoD) and the number of inspection opportunities
- Crack propagation time and inspection interval establish number of opportunities
- PoD based on ease and reliability of inspection technique
- Effectiveness = 1 – (1 – POD)^opportunities
- PoD is known = 0.98 (previous field experience)
- Effectiveness must be 1 – (2.1/166) = 0.987 for acceptable risk level
- Need to determine number of opportunities …

Monte Carlo simulation can be used to define the number of opportunities

β = 3.3
η = 10,000
internal = 12,500 average = 0.737

rand #	prop time	rand #	to insp	opportunities
0.994873	16550	0.393719	4921	1
0.876461	12505	0.287973	3600	1
0.550676	9346	0.07767	971	1
0.318674	7481	0.694998	8687	0
0.900052	12876	0.172216	2153	1
0.227668	6636	0.38728	4841	1
0.345408	7709	0.399121	4989	1
0.242513	6783	0.10123	1265	1
0.643483	10094	0.156377	1955	1
0.133946	5556	0.882748	11034	0
0.172155	6035	0.39903	4988	1
0.260567	6956	0.152348	1904	1
0.690451	10494	0.321238	4015	1
0.902921	12925	0.021577	270	2
0.496994	8925	0.318644	3983	1
0.306894	7378	0.675954	8449	0
0.740806	10952	0.030122	377	1
0.427717	8380	0.6751	8439	0
0.16245	5920	0.159917	1999	1
0.788049	11423	0.318979	3987	1
0.272988	7072	0.883633	11045	0

Effectiveness = 1 – (1 – POD)^opportunities

PoD = 0.98

Interval	Opportunities	Effectiveness
12,500	0.737	0.946
10,000	0.901	0.970
8,000	1.123	0.988

Required effectiveness = 0.987

Summary

- Ultimate fleet actions based on least level of pain to achieve acceptable risk
- In this example, an inspection interval of 8,000 (miles) would achieve keeping the risk under threshold.
- In general, this combination of using available data (or expert opinion if data is not available) along with the well-known Weibull distribution that describes ~95 percent of failure modes and Monte Carlo simulation illustrates how to achieve a threshold risk in environmental areas, safety risk, financial risk, maintenance of refineries, and can be extended to use in early design of almost any product or process.

Notes

1. Monte Carlo simulation in this example used Excel. Monte Carlo simulation can be done with programming languages (C++, FORTRAN, etc.), MINITAB JMP, MATLAB, and many other packages.

2. Describing crack propagation with a Weibull distribution is not usually the case, most often crack propagation is lognormally distributed.

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