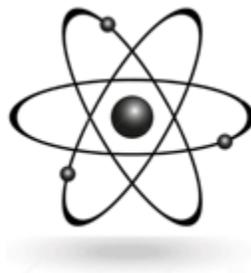


Global Quality Management Advisors



Nuclear Management Systems



What Energy Sector Executives Should Know About the Management of Nuclear Quality

White Paper

November 2018

February 2026

This paper, published November 2018 (not peer reviewed), is being updated to include information on the now fast-emerging growth in the global nuclear energy industry ~ 'A True Renaissance.' The updated version should be completed by April. Some content forms the basis for my book and the Nuclear Management System executive course under development.

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The U.S. nuclear industry encompasses a span of approximately 70 years including commercial, government, private, academic entities, and a variety of investors. The evolution consists of two general periods of research, development, design, procurement, manufacturing, construction, operations, reactor life-extensions, and most recently decommissioning programs. The periods are 1950~1999 and the “2000 Nuclear Renaissance.” I address what I know about the ‘Management of Nuclear Quality’ during these periods in this article. Of course, doing so in considerable detail would result in a multi-volume book publication.

The U.S. Atomic Energy Commission (AEC) was the original government regulatory body. The name was changed to the U.S. Nuclear Regulatory Commission (NRC) to ensure the public it was in fact a regulatory body. Industry criteria were enacted by federal regulations and industry committees developed supplemental codes and standards. This mandate triggered the need for writing clear commitment and implementing program documents. Three regulations formed the basis.

- U.S. NRC Title 10 Code of Federal Regulations, Part 50, Energy, “Domestic Licensing of Production and Utilization Facilities.”¹
- 10 CFR Part 50, Appendix A, General Design Criterion 1, included reference to Quality Assurance Program requirements as “Quality Standards and Records.”²
- 10CFR50, Appendix B “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities.”³
This CFR set the precedence for the industry to have formal quality programs among all entities. Practitioners refer to it as Appendix B or the “18 Criteria.”

The second period beginning in 2000 “The Renaissance” is the industry restart since the U.S. commercial nuclear power plant accident at Three Mile Island (TMI), Harrisburg, PA, in 1979. The entities previously mentioned above continue the pursuit of demonstrating the reasons why nuclear energy must continue as a key part of the energy mix. Major investments sustained the first period and helped propel the second period of new reactor concepts, safer designs and materials, small reactor applications, improved constructability, cost reductions and constraints, improved operational safety systems and equipment, a small but consistent supply chain, and a highly knowledgeable workforce and academic offerings for the next generations.

Figure 1 depicts events that shaped and impacted the industry to present times. It should be obvious the industry is still challenged to continue support, investments, growth, and public optimism. Those of us involved in the industry know it is unique, has faced numerous challenges, deals with concerns and scrutiny, ever increasing requirements, and still offers boundless possibilities.

Quality in our work lives is centered on meeting requirements. Doing things right is integral to our human belief system. The need to do things right always tugs at our thoughts and feelings and adds pressure for some. Philip B. Crosby, a quality thought leader in the 1970s, recognized this and addresses it in his well-known book “Quality is Free,” 1979.⁴ He revealed his concept of “Doing it Right the First Time” and his definition of Quality as “Conformance to Requirements.”

Do we all agree on what quality is? Will our customers accept our levels of quality? Do we always do the right thing the first time? Many other questions arise as we think about our product and service deliverables. Crosby's book was the first I read about quality and it confirmed I was in a profession that aligned with my beliefs. A considerable increase in articles and books followed during the '80s along with quality consulting and service offerings.

One day in 1973, I left the engineering design group in a manufacturer in Toledo, OH to work in the quality organization of one person at that time. I simply raised my hand, told management I wanted to help start the Nuclear Quality Assurance Program, and walked down the narrow hall to help Scott Gibbney move the program forward. We didn't know at that time the company would fast become the industry's supplier of choice for safety-related air management equipment worldwide. I wasn't sure what I signed up for, but like numerous other professionals back then I knew our country had plans to build over 100 Nuclear Power Plants (NPPs). It was an extremely bright future for a person with a young family and an interest in power generation. I had "jumped without a parachute" in the past, I just didn't know it would be the beginning of a 45-year career in Nuclear Quality. Nuclear Quality/Safety/Compliance became my passion.

In 1976, I moved from Toledo to join a large mechanical contractor, followed by an engineering/design firm, a major nuclear utility (Entergy Nuclear Operations), and then 25-years growing my nuclear quality consulting firm. My recent years of reflecting on a multitude of experiences compelled me to share what I consider the need-to-know aspects of quality in the nuclear energy industry.

Quality is management's discipline which must be understood, unconditionally endorsed, and pursued by every employee. The concepts, principles, and desires for excellence are common across all industry and business entities. Philosophies on quality are typically company-specific, customer-specific, and personnel. This brings perception, experience, and workplace-specific application of quality as a management discipline to center stage. Consensus is the daily challenge for achieving excellence.

The goals are offered for your awareness, advantages, planning, discussions, problem solving, and improvement efforts. My personal desire is to help the next generation as they rapidly move this most unique technology forward.

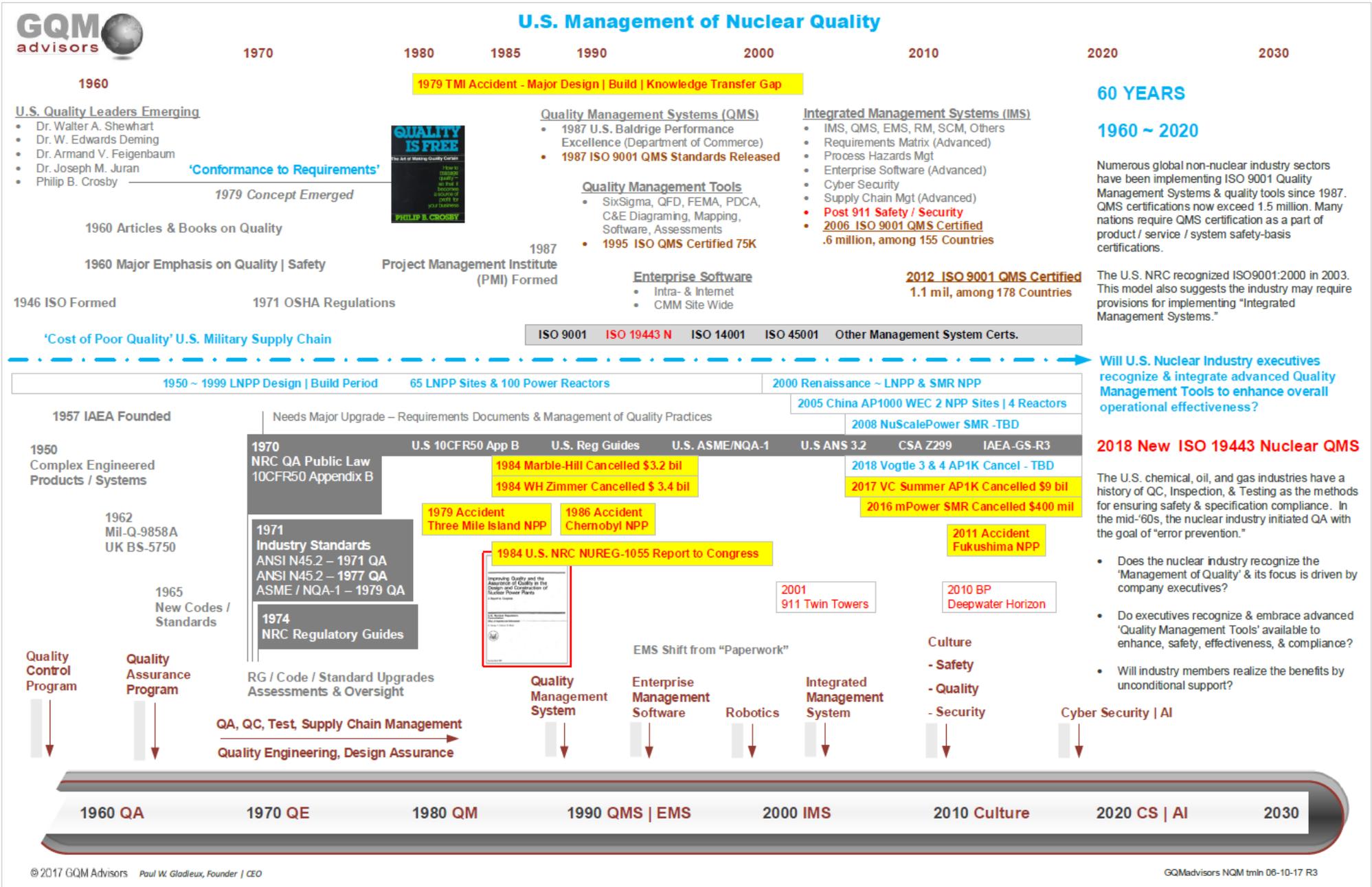


Figure 1

Article Goals

One Enhance the understanding of principles, practices, dynamics, issues, concerns, lessons learned, and other challenging aspects of maintaining consistency while improving quality. We all deal with perception differences in our efforts to manage for quality. This article reveals some impacts if quality is not understood, agreed upon, and consistent. From my experience, unplanned impacts and the lack of preventive measures are not unique to the nuclear industry. I address some of the causal factors. It is important that executives and their entire workforce have a solid basis for defining and ensuring quality expectations.

Each management discipline has unique terms. It is important to know some quality-related terms still cause confusion. They are quality, safety-related, important to safety, quality-related, quality policy, self-inspection, quality standards, quality control, quality assurance, quality management, quality program, quality system, quality improvement, quality management system, integrated management system, item, quality tools, statistical process control, six sigma, lean manufacturing, and process mapping. My reason for stating this is to reveal how overwhelming the language of quality can be and hopefully influence some of you to learn more about the discipline. Complete listings are available online in industry-specific regulations, codes, and standards.

Those working in the industry know that nuclear ‘safety-related’ items must meet applicable ‘quality levels’ delineated by specifying organizations in contracts, regulations, codes, and standards. This is the basis for the Quality Assurance (QA) discipline beginning in the late 1960s. Its original intent was to ensure specification conformance of NPP Structures, Systems, and Components (SSCs). The most critical QA activity is verification and reporting. As the industry matured, the scope of QA increased. It is still the predominate term used to address quality. The requirement for a ‘Nuclear Quality Assurance Program’ has been mandatory since the release of Appendix B.

Two Help industry entities recognize and agree on the need to broaden the current scope of quality practices throughout organizations. Broadened scopes are typically driven by customers, and organizations as they strive for improvements. It’s typical for companies to write additional process descriptions and procedures to cover broadened scopes. My desire is to help the industry recognize that Quality Programs are ‘Limited in Scope’ and they need to be broadened to ‘Full-Scope’ Quality Systems.

Perception, philosophy, definition, regulatory and customer expectations, agreement, training, and lessons learned are some essential elements as the basis of change. The industry has gone through numerous changes and technical advancements since the 1980s. This is evidence of quality improvement. There is still confusion about quality due to perception issues, some of which are ownership of quality. ‘Quality System’ still infers the quality department has ownership. The only place it states that top management owns quality is in the classical Quality Policy Statement that has limited readership and ongoing awareness.

I am not suggesting a change in quality just in terminology. I believe using ‘Nuclear Management System’ (NMS) v. ‘Quality Management System’ (QMS) will virtually eliminate potential confusion in the workforce. The industry would further reduce deficiencies, violations, stand-downs, cost overruns, large sums of investments, public concerns and skepticism, and frankly design/build program failures with such a change in terminology.

Three I believe it is important for the industry to recognize the need for distinct new job roles. I take the position that executives, upper management, directors, and managers need an advisory level professional (NMS Advisor) regarding regulatory, legal, and interpretation aspect of their management system. There is also a need for a professional able to design and maintain the framework, infrastructure, interfaces, and requirements management of the overall system (NMS Designer).

Language of Quality

The following terms and quality disciplines should be understood to effectively implement nuclear quality requirements. ⁵

Terms

Quality Conformance to Requirements

Quality Policy The overall quality intentions and direction of an organization regarding quality as formally expressed by top management.

Quality Management System (QMS) The organizational structure, processes, procedures, and resources needed to implement quality management goals, objectives, and requirements.

Four Quality Disciplines

Quality Leadership (QL) The Department of the Navy’s definition of QL is based on Dr. W. Edwards Deming’s ideas. “The application of quantitative methods and the knowledge of people to assess and improve a) materials and services supplied to the organization, b) all significant processes within the organization, and c) meeting the needs of the end-user, now and in the future.”

Quality Management (QM) That aspect of the overall management function that determines and implements quality policy. Quality management includes strategic planning, allocation of resources, and systematic activities for quality such as quality planning, operations, oversight, and evaluation.

Quality Assurance (QA) It comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements. Source: 10CFR50 Appendix B ³

Quality Control (QC) Those actions that provide a means of control and measure of the characteristics of an item, process, or facility to established requirements (inspection or source surveillance, or both).

Quality v. Safety

I mentioned the Three Mile Island NPP accident which caused the industry to stop reactor orders, some design / build progress, and maturation of the supply chain. Most importantly, this impacted a much-needed transfer of cumulative

industry knowledge that spans 50 years to the next generation. Figure 1 puts this into perspective and should help you realize why there is a continued challenge to prove the value of the 2000 Renaissance efforts.

The general processes of designing, building, and operating high-consequence facilities and structures such as chemical plants, oil refineries, environmental sensitive factories, nuclear facilities, and bridges are fundamentally the same. Bringing together structural steel, concrete, electrical cables, rebar, heavy doors, steel cat walks, piping, HVAC systems, high-strength fasteners, computers, valves, pumps, etc. to build a facility are common elements.

Some key differences pertain to the nuclear safety design basis, margin-of-safety, applicable quality-levels, radiological parameters, design life of the facility, personal safety, defining and managing for quality, protecting the public and environment, ensuring low risk to investors, and being good stewards of our world.

I consider a recent article timeless for gaining a modern viewpoint regarding the management of quality and safety. It can be read with any industry application in mind. It reveals some critical generic aspects of quality and safety. The American Society for Quality published the article in *Quality Progress*, September 2013, by Mr. Mustafa Ghaleiw (management systems group, Shell Oil Doha, Qatar) entitled “Quality v. Safety, Priorities at Odds in the Oil and Gas Industries.”⁶ He begins by citing a personal blog entry by Dr. Lowellyne James, a lecturer at the Aberdeen Business School in the United Kingdom. Dr. James states “The absence of a quality culture gave rise to six serious quality management failures” regarding the 2010 BP Deepwater Horizon oil spill in the Gulf of Mexico. He continued to state, “these failures caused a tragic loss of life and catastrophic environmental disaster.” Mr. Ghaleiw states in his article “the absence of a quality culture cost BP a \$91 billion drop in market value in 2010 and sparked 350 lawsuits.”

Programs and Systems

The terms program and system are used today to describe the management of quality among entities throughout the world. The perception they are the same in scope and application is not true. It depends on each person’s experience, training, academic orientation, contract language, business sector, and perceptions.

My position on using program and system as defined and intended is not new. I’m compelled to share it now considering news about continued program failures, recurring deficiencies from those during the first design/build period, and prevention options as Small Modular Reactor (SMR) programs rapidly move forward. Lessons learned from the first period offer the SMR designers and builders the insights for preventive measures.

Program v. System - Some believe a quality program and a quality system are the same and use the two terms to address the same thing. This is at the heart of not understanding the proper of use of quality terminology and the perception problem discussed later.

For simplicity, a program is limited in scope regarding a function or discipline such as personal safety, nuclear safety, engineering/design, quality, contract management, supply chain management, training, software code controls, etc. A system is dynamic and full-scope to encompass the spectrum of operations such as plans, policies, programs, activities, tasks, projects, procedures, and instructions in a company. It is open ended by design to allow additions and modifications as directed by the CEO and other executives.

Quality Management System (QMS) - Term usage began after the release of the international standard ISO 9001 “Quality Management Systems – Requirements Standard,” 1987.⁷ Its use is generic across all business sectors. U.S. nuclear industry companies began evaluations of requirements in the standard and aligning existing quality program commitments in the late 1990s. The American Society of Mechanical Engineers (ASME) QA committee has compared the requirements in ASME NQA-1, “Quality Assurance Requirements for Nuclear Facility Applications”⁸ with ISO 9001. The NRC includes position statements for use in application. Westinghouse Nuclear was the first major supplier (NSSS) to achieve ISO 9001 QMS certification.

Nuclear Management System (NMS) - I see the use of Nuclear Management System v. Quality Management System as the most effective way to eliminate the probability of an individual or groups confusing the intent, scope, applicability, content, commitments, and ownership of the Management System. The word quality can infer that management system ownership belongs to the quality department or group. Using the term nuclear management system greatly reduces the probability of confusion and reinforces ownership by company executives. Executives that do this internally and external to the company will be taking a much clearer position on the ownership and scope of their management system.

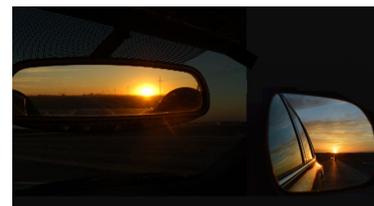
“Our Nuclear Management System is Focused on Quality”

If asked “is your NMS the same as a QMS” the answer is Yes. “We eliminate confusion about who has complete ownership of our system.” If asked about a QA Program the answer is Yes. “We know QA is our discipline for systematic methods of verifying and reporting conformance to requirements. This is one of our programs in our NMS.” If asked about a QC Program the answer is Yes. “We know QC is part of QA to ensure physical characteristics conform to requirements using inspection and testing methods. This is one of our programs in our NMS.”

Please keep the following in mind as you read about the two periods encompassing 70 years. Those working in the industry know there are millions of requirements that must be identified, managed, verified, and ultimately met as specified. Effective requirements management across and down the organizations is paramount. Licensees (Owners), Designers, Contractors, Subcontractors, and Suppliers are required to demonstrate conformance at any time during the work. NPP startup and operations will not be approved without conformance verifications and approvals. **Nuclear Management System** should be the industry standard term with the variety of programs defined & managed within its scope.

1950 ~ 1999

Since the 1950s, the ideas for commercializing nuclear applications have presented limitless possibilities. In 1953, U.S. President Dwight D. Eisenhower, announced the “Atoms for Peace Program”⁹ at a United Nations General Assembly and recommended the formation of the International Atomic Energy Agency (IAEA) for oversight of the peaceful use of nuclear materials. To begin to harness nuclear energy for peacetime use, the agency and individual governments and its contractors started the development of nuclear-specific regulations, specifications, codes, and standards while building research/test reactors.



“Those who cannot remember the past are condemned to repeat it.”¹⁰

When design/build activities commenced for the first NPPs in the early ‘60s, utility management assigned people from the coal and oil-fired power plants. They did not know at that time all the significant differences that would emerge using nuclear fuel and facility needs for complex safety-related requirements. They did not know specific risks and required system safety margins, environmental impact potentials, fuel sensitivities, system dynamics, and other required controls. Going forward, these requirements would affect how NPPs would be designed, fabricated, built, and operated. How could they know without findings and reports from monitoring all aspects of this new form of energy?

The general belief by the utilities was they have been building large structures and power plants for decades. Using nuclear fuel would cause some differences relating to nuclear and personal safety, and the environment. The government and contractors knew there would be some differences but not to the extent later revealed.

As researchers, scientists, engineers, and builders revealed increased complexities in plant design for controlling nuclear materials, operating conditions, and radiation protection the need for higher quality all SSCs became obvious. This included highly skilled craft, technicians, a robust supply chain, and information controls.

Soon the need to locate and operate the reactor systems from a remote operating room and other “contained” locations throughout the plant became a reality. Engineers knew this would require higher levels of material integrity, reliability, nuclear safety systems, and personal safety management. This created the need for new design basis parameters, new operating philosophies, advanced materials, an isolation containment structure for the reactor systems, and methods to limit containment access and radiation exposures. This also created the need for managing a large increase in requirements. It was expected that all organizations would have higher quality and safety measures, improved supplier performance, document and records management systems, accurate information, training, and effective business processes. With a design-life of 40 years, these truths became evident.

The need to account for ‘total compliance to requirements’ resulted in the need to implement effective technical and administrative controls. Mandatory regulations and standards were identified by ‘Shall’ statements while recommendations were the ‘Should’ statements. This approach is true today.

Clarifications on the use of legal-related terms such as shall, should, might, may, will, and can were provided. It formed the basis for contract language, manuals, procedures, and test instructions. Time would reveal that these terms were ignored by some as critical to the work. Eventually, the industry began to realize the direct relationship between quality and the law. Lawsuits amplified awareness in this area of concern not without fraudulent actions revealed to the public.

By the late 1970s, the design, procurement, and construction of many NPPs were at various phases of completion. Applying the new regulations and industry standards added strain on the supply chain and the utilities already in the fast-track to operate new plants. The learning curve for new requirements and interpretations was intense.

The first period represented initial government agency involvement, the basis for licensing criteria, R&D authorizations, development of research sites and reactors, first commercial power reactors (Shippingport and Dresden). It laid the groundwork for the design, build, and operation of the first fleet of 100 plus commercial power reactors located at several U.S. sites. It began a knowledge transfer to those in R&D and academia.

It was the formation period of requirements for improved technical controls, requirement interpretations and implementation, basis for resources, and the need to understand the new demand for improved administrative controls. The administrative needs continually trailed the technical development aspects and plant startup activities. It should be noted administrative provisions still trail technical aspects. The industry is highly technical. Quality is considered highly technical. The administrative needs are perceived as highly technical when in fact they are administratively complex. I believe business management professionals are the strong fit for the administrative side of programs and operations.

During this evolution, the work approach from ‘Error Detection’ (inspection) to ‘Error Prevention’ (strategic quality planning, quality engineering, training, prototyping, advanced management systems, etc.) emerged and revealed numerous benefits. Over the past 100 years the quality profession, “backed its way into various industries as a needed discipline in order to meet product and service expectations.” It’s among other disciplines such as safety, human resources, procurement/contracts, information technology, computer-aided design, and now cyber security, robotics, and artificial intelligence.

Unfortunately, the industry was hit hard by the accident at Three Mile Island NPP in Harrisburg, PA in 1979. The accident set the precedence for investigations among several build sites by the U.S. NRC as directed by the U.S. Congress.

The results are described in the Report to Congress, U.S. NRC NUREG-1055-1984, “Improving Quality and the Assurance of Quality in the Design & Construction of Nuclear Power Plants.”¹¹

The report revealed a wide range of ‘quality-related problems’ that made it clear the industry did not have the proper resources, effective management systems, and understanding of quality and safety in place to plan and execute the design, build, and startup of complex NPPs. Unfortunately, it caused a supplier resource gap for over twenty years. Most importantly, it created an impact on effective transfer of knowledge to the second generation. It remains a problem today.

2000 U.S. Renaissance

The U.S. nuclear industry second growth period began in the year 2000. The two U.S. industry-based initiatives that emerged to demonstrate commitment were NuStart Energy Consortium 2005 and Unistar Nuclear Energy 2007. These collaborative efforts demonstrated the optimism and desire to bring the industry back as a viable energy source. The goal was to share resources and improve standardization of overall plant designs, systems, construction methods, operational processes, and a well-trained workforce.

The renaissance includes new concepts with advanced fuel designs, inherent safety system improvements, enhanced plant standardization, robotics, and improved software. Small Modular Reactor (SMR) NPPs bring promise for site locations not conducive for large plants. Now the question - is the industry already condemned by repeating the past? Two recent U.S. examples of NPP failures occurred in 2017. They are the Westinghouse Nuclear, VC Summer NPP, AP1000 Reactors, Columbia, SC and BWX Technologies, mPower SMR Program, Lynchburg, VA. The first major impact at an operating facility in decades was the accident in March 2011 at Fukushima Daiichi in Japan.

While the number of potential new plant owners and proposed sites continue to grow globally, the U.S. struggles to demonstrate the ability to deploy new plants in a cost effective and compliant manner. There is a clear shift towards ‘smaller is better’ with the number of entities and investors focused on the viability of SMR technology. It seems every day there is an announcement about a breakthrough giving the industry continued interest and optimism. Fusion is now in the news and seems viable for the first time in decades. Small reactor technology development is very active at various phases of research. Some programs include the Traveling Wave Reactor (TWR) and Molten Chloride Fast Reactor (MCFR)¹², NuScale Power Module™, LWR, Nu™,¹³ and the Integral Molten Salt Reactor (IMSR).¹⁴ U.S. NuScale Power awarded U.S. BWX Technologies the contract for reactor fabrication September 2018. Also see the following websites for the WNA.¹⁵

- World Nuclear Association (March 2018) Small Nuclear Power Reactors (SMR) website: <http://www.world-nuclear.org/information-library/nuclear-fuel-cycle/nuclear-power-reactors/small-nuclear-power-reactors.aspx>
- World Nuclear Association (August 2017) Advanced Nuclear Power Reactors website: <http://www.world-nuclear.org/information-library/nuclear-fuel-cycle/nuclear-power-reactors/advanced-nuclear-power-reactors.aspx>

Impacts on Quality During Design | Build

Beginning in the 1960s, there was a large step in formality and practices for safety-related and high consequence applications. This inherently added to the formality and broader scope of quality practices and procedures. By the late 1970s, issues emerged such as inconsistency, incorrect information, poor traceability, and even some cases of fraudulent documents and records. There was not a uniform understanding that pedigree (‘paperwork’) of the work and SSCs, was a key aspect of ensuring quality and the ability to demonstrate conformance.

Too many workers did not know the pedigree requirements were embedded in contracts and specifications as part of the method to capture evidence of conformance. Jokingly, some suppliers were told by their customers “when the paperwork equals the weight of the equipment, you can ship it to the site.” In one case I had to agree. Unfortunately, it was perceived and generally adopted that “QA takes care of all that paperwork.”

The actual goal was to demonstrate you had complete control and traceability of SSCs, activities, tasks, and deliverables as specified. This meant you could show completed tasks and approvals of the steps described in procedures and other governing documents. You had evidence documented that could be used to ‘reconstruct the chain of events,’ if required. Document/Data Packages were deliverables to the NPP site for review and acceptance prior to release items for installation and operational use. Some suppliers struggled with this requirement and caused schedule impacts at the sites. They were not good at ‘doing the paperwork.’ This created a work environment of ‘suspect work and materials.’ It caused friction among contractors.

To make it clear as to the importance of doing the paperwork, some in the lower supply tiers were asked by owner representatives “do you want to enter a hot (nuclear) pressurized containment structure to determine why your material/equipment failed and caused a reactor shut down?” Does your company want to explain to the owners and regulators why your products failed and what you will do as corrective action? Can your company afford impacts on cost and industry news about being investigated? If you didn’t get the point why your documentation must be traceable and the products were reliable, then you needed to leave the industry. Plants in the late ‘70s were cancelled because of poor document management and loss of traceability. I witnessed this at the Marble Hill NPP site in Indiana.

This is why a strong understanding of the Quality discipline intent, roles and responsibilities, and accurate word usage must be established. Remember my reference to the U.S. NRC Report to Congress NUREG-1055 regarding quality improvement? Normally job titles tell us roles and responsibilities that we generally understand. A simple look at job search websites reveals a vast number of titles in quality job roles. Some job postings list over 50 line-items of activities and tasks. It seems the longer the list the less the employer knows about the role. It seems they don’t want to miss anything to have the company be ‘perfect.’ Their belief is the person working in the quality role will make the company perfect. This couldn’t be further from the truth.

There are no international standard job descriptions for quality's role in the various business sectors. If you look for CPAs, Engineers, Welders, Draftsmen, Purchasing Agents it seems straight forward. In many cases, customers' definition of quality and supplier expectations cause this ongoing issue.

I continue to see posted positions for QA Managers that do not make sense. Most postings have 50 bullet items, and the candidate only needs three years of experience; the list goes on and on stating numerous details that encompass the work of five people. It's clear the company has no idea what their need is and what the position entails. To address this problem, a dozen generic positions for the quality profession should be established by a common international accredited body - perhaps four defined positions in each of the disciplines (quality leadership, quality management, quality assurance, quality control). Clear roles and responsibilities are critical for effectiveness and success in meeting quality requirements.

I've worked around individuals that fully embraced quality to those who literally turned around and walked the opposite direction for fear of engaging with me. I've been in boardroom meetings. I've been told quality has no reason to be in project or executive meetings. In some cases, I was intentionally not notified for special project team meetings. I've been told quality has no business reviewing requests for bid, contracts, purchase orders, and design change notices.

It's unfortunate during the first era that many workers were wrongfully fired because "they didn't catch deficiencies and were perceived as not doing their job." Many Quality Managers, Quality Engineers, and Inspectors were fired only because of no clear understanding of roles and responsibilities. Some of this stemmed from the coal and oil-fired boiler plants where final inspection was the method to determine if everything was acceptable. This error detection method caused needless cost impacts and tension among the workforce. Quality control inspectors were considered troublemakers. Some of the joking reduced the importance and value of quality in general and the job roles. Most often that behavior is the product of uncertainty, fear, and no management commitment. The major shift in perception and improvement will only happen when the Chief Quality Officer (CQO) is an active member of the "C" suit. Westinghouse Nuclear was first to appoint a CQO.

QA for error prevention v. QC for error detection became the new approach. This opened the door to establishing administrative methods to ensure conformance to requirements as the work was performed versus after the fact. The formality was new and the procedural controls were extensive compared to fossil plants. Formal quality practices did cause confusion especially since people didn't want others to look at their work. It was perceived as slowing down the work when in fact it revealed weaknesses or failures in work processes and procedures. At times, I had to explain what my job was while doing the work. It still happens today in the U.S. nuclear industry for some individuals. I hear from them since they are seeking solutions.

The strong threatening words in the title evoke an emotion of fear. Pointing and looking down while having the word Quality in the readers mind likely emblazoned an image that QA was to be feared. This meant anyone in a QA job role must be feared. This made workers in QA analogous to the “company police.” The imagination can go the wrong way without clear understanding of job roles up front. Employees relate a job role with the job title. Purchasing purchases, accounting helps manage cost, engineers/designers create products, and so on. Hence, the title of this article sent the message that a nuclear government entity had to “Bear Down on QA.” I’m positive that people took that to mean QA needs to “do your job.” Word of mouth in the early days formed some of the perception that unfortunately exists to this day. Quality is to be feared in lieu of embraced. Avoid those workers in QA. Don’t offer any information about problems because ‘they will write you up.’

The job role in the early ‘70s was intended to be the “eyes and ears” for engineering while being separate from production pressure with its own formal reporting structure. It was initially an adjunct to the engineering department. Unfortunately, this was not understood throughout the industry. Some organizations thought employees in QA were responsible for finding errors and fixing them as well!

The image of two men in suits looking down just in this one article did not help. Common sense would tell you they were having discussions about the build. People doing the work however, more than likely felt some level of fear seeing these men. Workers talk. Rumors spread. Opinions are formed and retained. The content by the author was valuable but the one photo and a poorly worded title affected some readers.

So, what was QA? Was it hunting for mistakes? Fixing problems? Was it exposing untrained employees and causing trouble? Was it getting people fired? Were those in the QA job role worried about getting fired for doing their job? Were they holding up production or a developmental program? Was it telling others what to do? Shuffling papers? Was it a job for underperforming employees? Have these perceptions changed?

There must be an improvement in understanding and consistency. The world of business is moving faster which demands seamless product and service conformance, performance, and delivery. Everyone wants to do a good job and please others. In the U.S. nuclear industry, old views of the quality role must change. Highly skilled craft and professionals now come from different sectors and segments. Quality management, quality assurance, and quality control are not defined and implemented the same way as other sectors such as aerospace, non-nuclear construction, oil/gas exploration and refining, healthcare, and pharmaceuticals. It must be understood that companies hire employees from different sectors.

Education is only one way to correct the misperception of quality among the workforce. I’m talking about correcting the perception of what quality is, why it is integral to everything we do, how to leverage from quality management tools, and commit to continual improvement practices.

Top management must wear quality on their sleeve, understand and use the quality language to demonstrate it is center to the operation. Whatever quality is in each sector and organization, unless top management understands what it is, why it is critical to the operations, how to define and implement measures for managing quality, and when and where it is applicable, Quality will not be understood. It will remain a confusing point of contention and viewed as an operational hinderance. Unless top management owns it like safety, cost, schedule, and satisfied customers, acceptable levels of quality will not be achieved. Lack of quality will be the reason for lost contracts and future customers.

Terms, definitions, and word usage in each operational discipline matter and need to be used as appropriate throughout the organization. If quality is the responsibility of each employee, then how can just the person in QA ensure quality? Employees working in QA roles merely verify levels of conformance to requirements. Depending on the size of a company, there can be millions of requirements for the delivery of products and services. QA does not ensure conformance to every requirement.

The nuclear industry by the late '70s, prior to the TMI accident, began to stabilize across the supply chain and build sites. A few U.S. build sites experienced major non-compliances with some regulatory violations. Two well-known build sites were cancelled in the early '80s (Marble Hill Plant in Indiana and WH Zimmer Plant in Ohio). Construction at both sites terminated at an approximate cost of \$2.2 billion (each site). They had a history of Inspector intimidation, loss of design control and document management.

From an historical standpoint, perhaps you wonder why the first design/build period should matter now considering the advances in technology. Some believe the first era is 'old school' and belongs in the history books. Some will say we will do a much better job with the use of computers, IT, robotic equipment, electronic devices, design modeling, inherent safety systems, improved materials, construction methods, internet, and instantly accessible information. These will reduce time and costs, but will it improve quality? Figure 3 are some of the quality deficiencies addressed in U.S. NRC NUREG-1055. Some have already been repeated since the beginning of the 2000 Renaissance. An effective NMS will prevent these and other non-conformances.

Quality-Related Deficiencies

- Inadequate Quality Inspection Documentation
- Inadequate Reporting of Nonconformances
- Drawing Deficiencies
- Inadequate Specifications
- Materials Control Deficiencies
- Inadequate Procedures & Instructions
- Procedure Violation
- Inadequate Licensee Audits
- Inadequate Corrective Action Programs

Figure 3

U.S. NRC Report to Congress, NUREG-1055

More questions arise. Are communication skills effective? Do we understand the plant complexities? Do we know the requirements and their intent? Are we truly qualified and trained? Will computers and IT really be the end-all? Will the workforce be consistent? Do we effectively implement requirements? Will management provide resources for the ability to “Do it Right the First Time?”

We all know fear in the workplace has negative impacts on a business. It inhibits creativity, self-motivation, feeds insecurity, reduces trust, causes finger pointing, and jeopardizes personal health. It can result in reduced profits, unsatisfied customers, and an environment that greatly reduces the goal of Doing it Right the First Time. Employees want unconditional trust. They go to work every day with the intention of doing a good job. They also need and must know what their job is. They must understand the job dimensions and environment.

Imagine twenty-five million workers going to work on the same day. At the end of the day no one made an error. What a perfect world. Some go home worrying about errors made that day. Some go home with their belongings in a brown cardboard box and won't return the next day. Their family and friends must deal with the bad news. Why in our modern age are employees still working in threat environments? Why is firing the American way? Why do American companies demand loyalty when you are hired and yet walk you to your car when terminated (a walk of shame)? The employee goes home and trouble is just beginning. Termination causes many issues including divorce, depression, anxiety, anger, and even suicide.

Quality Management as a discipline emerged in the '90s as the need for defining the scope of quality, planning, scheduling, determining capability, oversight, reporting at the program level, and briefings at the executive level. This new concept revealed greater understanding of why and how administrative and technical processes must seamlessly work hand in hand.

Dr. W. Edwards Deming is considered to be “The Father of Quality.” Two of many books he has authored and those written about him always address the human factor relative to quality and effective management systems. Here are two I recommend.

- “The Man Who Discovered Quality” (How W. Edwards Deming Brought the Quality Revolution to America – The Stories of Ford, Xerox, and GM), Andrea Gabor ¹⁷
- “The American Who Taught the Japanese About Quality,” Rafael Aguayo ¹⁸

Dr. Deming is known worldwide for his Fourteen Points of Management. The most noteworthy of which is “Drive out fear so that everyone may work effectively for the company.” What company would not want each employee to work effectively?

We have a saying in the U.S., “we can put a man on the moon, so why can’t we ___ (meaning we can do anything). There must be an operating method other than fear and termination that everyone can agree on. Perhaps companies will not have to stock brown cardboard boxes in the warehouse for employee terminations. Perhaps workers will not go home, stressed, disappointed, no income, embarrassed, and begin a period of self-doubt and worry.

Now, I’m sure you want to know why I had so much to say about the impact of quality on design and construction. During my 40 plus years gaining expertise in the quality profession, I often thought about the limited scope of quality in the nuclear industry. It’s a fact that the original U.S. regulation for quality 10CFR50 Appendix B was created as 18 criteria considered critical for ensuring safety-related SSCs conformed to requirements. This regulatory document remains intact as released in 1970. Since then, government and private entities have provided interpretations and training courses. Nuclear Quality Auditors must be certified to participate in audits. There are ongoing debates on the scope of quality as required by Appendix B. Most entities draw a line at just meeting the ‘Shall’ statements.

From my experience developing and implementing fourteen quality system startups and five upgrades, I keep coming back to two fundamental elements of management that will greatly enhance compliance during all phases of reaching NPP operational status. The number of phases may vary but the elements of management should always be the same. I could go on about the mission, values, quality policy, etc. - all the feelgood statements. I believe a *full-scope nuclear management system focused on quality* and an *effective requirements management process* leads to compliance. Of course, qualifications, training, well written policies/procedures, strong communications and numerous other factors are involved.

Requirements Identification | Integration | Verification

Quality is Conformance to Requirements It seems simple enough.

Requirement (noun)

- a thing that is needed or wanted, "choose the type of window that suits your requirements best"
- a thing that is compulsory; a necessary condition, "applicants must satisfy the normal entry requirements"

synonyms: need, wish, demand, want, necessity, essential, prerequisite, stipulation

For a moment imagine sitting in a large concert hall waiting for a well-known symphony to begin its magic. The Conductor enters, which always starts the evening with a long applause filled with excitement. Imagine it now very quiet for a moment - then with one tap on the pedestal sounds erupt. You see synchronized movements and wonder how the group flawlessly integrates their individual skills using such unique instruments. You try to imagine being a member of the orchestra. You try to hear, read, and play the music all simultaneously without errors. *Leaning forward you sit in that enchanting concert hall, then you sit back and think about how much commitment and effort it takes to learn your instrument, the time it would take to master it and the music, how disciplined you must be to harmonize among the group, and practice, practice, practice.*

The thought of an error causing the orchestra to stop doesn't even cross your mind. You know what point I'm making. So many readiness tasks – commitment – understanding – teamwork – time in practice and continual learning. So much patience to perfect harmony and joy for so many people. Hundreds of elements for individual and group success by *Conforming to Requirements. The orchestra focuses on 'Doing it Right the First Time.'* The Conductor implements her/his system - an effort we all understand.

The nuclear industry is faced with meeting hundreds of millions of requirements. It must be able to demonstrate conformance as the work progresses. The Requirements Management Matrix is a cornerstone document used to identify, integrate, and verify conformance. It is a key management tool that ensures the source of requirements. It must have input and support from the applicable discipline leads. The matrix is typically developed with those in the licensing group as well. It is the source document for developing plans, process descriptions, procedures, work instructions, audit and test plans, and other implementing documents. The matrix is a living dynamic document among the applicable disciplines with controlled distributions and accurate revision status controls.

 Requirements Management Matrix			
Purpose: Engineering Design Group By: Paul W. Gladieux December 2008, Revision - 0 -			
10 CFR 50, Appendix B	ASME NQA-1-1994	Quality Manual	Project Quality Plan / Procedures / Others
III. Design Control	BASIC REQUIREMENT 3, DESIGN CONTROL	Quality Assurance Program Description QAPD, Section 3	Type / Number
Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in-service inspection, maintenance, and repair, and delineation of acceptance criteria for inspections and tests.	The design shall be defined, controlled, and verified.	QAPD section 3	Plan, (section) 2.5
	Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents.	QAPD section 3.2, 3.3 QAPD limits design inputs to functional specs. Should be general.	Procedure, 2.1, 2.2, 2.3, 2.4,
Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	Design interfaces shall be identified and controlled.	QAPD section 3.10	Plan, 4.0
The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization.	Design adequacy shall be verified by persons other than those who designed the item.	QAPD sections 3.5,6,7,8	Plan, 2.8
Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.	Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.	QAPD 3.9	Plan, 3.0 Procedures - TBD
	SUPPLEMENT 3S-1 SUPPLEMENTARY REQUIREMENTS FOR DESIGN CONTROL		
	1 GENERAL		
	This Supplement provides amplified requirements for design control.		
	It supplements the requirements of Basic Requirement 3 of this Part and shall be used in conjunction with that Basic Requirement when and to the extent specified by the organization invoking this Part.		
	2 DESIGN INPUT		
	Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards, shall be identified and documented, and their selection reviewed and approved by the responsible design organization.	QAPD section 3.2 QAPD limits design inputs to functional specs. Should be general.	2.3
	The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.	QAPD section 3.2 no "timely basis"	2.4
	Changes from approved design inputs, including the reason for the changes, shall be identified, approved,	QAPD 3.9	3.0

Figure 4
Requirements Management Matrix

Here are a few requirements documents that may require analysis for applicability, commitment, implementation, and the ability to demonstrate conformance. Never forget to review the legally binding documents first because those form the true baseline of the requirements documents.

- U.S. NRC, “Quality Assurance Program Criteria (Design and Construction),” Regulatory Guide 1.28
- U.S. NRC, “Quality Assurance Program Requirements (Operation),” Regulatory Guide 1.33
- U.S. NRC, Generic Letter 84-01, NRC Use of Terms, Important to Safety” & Safety-Related”
- U.S. NRC, SECY-03-0117 Policy Position on ISO 9001-2000 “Quality Management Systems – Requirements Standard”
- U.S. Nuclear Regulatory Commission (NRC), NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” Section 17.5, “Quality Assurance Program Description- Design Certification, Early Site Permit and New License Applicants,” (ADAMS Accession No. ML15037A441)
- NRC, “Guidance on Managing Quality Assurance Records in Electronic Media,” RIS 2000-18

Each organization needs to research, track, evaluate, and make notifications of new and revised requirements documents.

Here are a few examples.

- ISO 19443:2018 Quality Management Systems – Specific requirements ¹⁹ for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS). It was developed by Technical Committee ISO/TC85 – Nuclear energy, nuclear technologies, and radiological protection.
- ASME/NQA-1-2015, Subpart 4.2, “Guides on Application of NQA-1 to Work Processes and Activities” ²⁰
- ASME/NQA-1-2015, Subpart 4.2.1, “Guidance on Graded Application of Nuclear Quality Assurance (NQA) Standard for Research and Development” ²¹
- ASME/NQA-1-2015 subpart 4.1.5, ANS-15.8, “Quality Assurance Requirements for the Design, Construction, Operation, and Decommissioning of Research Reactors” ²²
- IAEA GS-R-3 Standards include matrixed analysis of ASME/NQA-1, ISO 9001, and other industry-related documents.

A point of contention throughout many business sectors in the 1990s was the applicability of the ISO 9001 QMS standards. For the first five plus years, many U.S. corporations believed the standard was only applicable to European organizations. One of the original reasons for the standard was to ensure organizations internationally had common management system elements for ease of procurement among nations.

The technical committee’s goal was to eliminate over four hundred standards for quality. The CE Mark is the safety compliance designation for acceptable products in the European Union (EU). The ISO 9001 QMS standards became the management system to document and demonstrate compliance. Product labelling encompasses everything from automobile parts, toasters, cell phones to medical devices and construction equipment.

There are now over 1.5 million ISO 9001 certified companies. The U.S. nuclear industry supply chain is faced with meeting applicable requirements in the standard when required by contract. There are other related ISO standards to meet as applicable with contract and nationally adopted requirements.

NRC NUREG-1055, provides the basis for nuclear management system improvements and compliance. Since 2000, the U.S. NRC has pointed the overall industry towards the lessons learned in the Congressional Report. If quality in the U.S. continues to be ~~to~~ third to cost and schedule, the future of nuclear energy in the U.S. will fail. Quality and safety must be first among equals. The industry has an opportunity now more than ever to not repeat the past.

Nuclear Management System (NMS) - Advisor | Designer

Goals two and three in this article blend here as I discuss the NMS and the need for Advisors and Designers. More than ever, executives must recognize their management system requires effective “*systems thinkers*” to lead conceptual definition, define baseline requirements, development content, sustain effectiveness, and manage required upgrades. The initial plan, scope, framework, structure, and baseline requirements set the direction for the NMS.

Workers today need to be ‘systems thinkers’ and do their work while thinking systemically ‘connecting the dots.’ This means effectively communicating across, up, and down the various internal and external locations of the work. Don’t just pass the work on to the next in line; instead verify your work and ask peers to challenge your work often. The information flow today is dynamic internal and external to the programs and operations.

Poor communications and requirements management can be catastrophic as the number of individuals increases. Communication models demonstrate the geometric progression factor. A meeting of six individuals demonstrates the dynamic. Figure 5 shows the potential for thirty lines of communication. It wouldn’t take much to calculate the vast potential lines as more individuals are included. Risk mitigation driven by a very effective NMS is the best method.

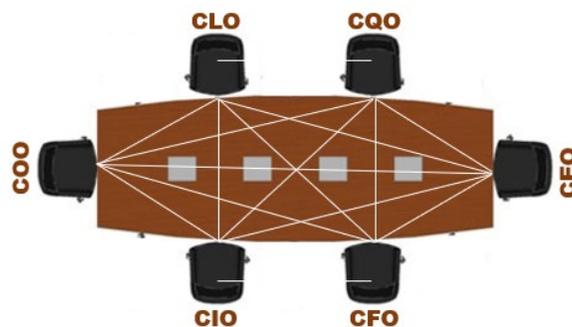


Figure 5

Communications

Over the past twenty-five years the role of a “Computer Software Architect” emerged from the need to define and layout the network structure of complex enterprise software. The internet and personal computer era entered the workplace ~~in~~ ~~the~~ and our personal lives in the ‘90s. I remember it well. We began discussions about learning and using the computer

system. That term fast became part of the American and global lexicon. When using that term today most people think of a computer system. When using the term management system most people think of a computer system. The goal of using the term NMS is for people to think of the company policies, procedures, instructions, and other business documents. The information that drives the business.

It's interesting that people grasp what computer system workers do, but typically do not grasp what a management system worker does. Major challenges include working through the layers of requirements, ensuring effective interfaces among the disciplines, and documenting what is required based upon commitments and procedures in the system. Just as the software architect role emerged, now there is a need for specific NMS expertise.

I believe the best position descriptions are NMS Designer and NMS Advisor. I see a scheme to achieve NMS Designer qualification status and then achieve NMS Advisor certification status. The concept is like the Project Management Institutes PMP Program for professional certification. A few years ago, I began developing course materials encompassing the required body of knowledge for each position. Our dynamic business world now requires robust enterprise information management platforms. These positions will complement our modern way of using accurate and timely information.

NMS Advisor - The role requires an extensive body of knowledge encompassing administrative and technical skills. The individual must know how to design an NMS, be an excellent communicator, demonstrate word mastery, have technical flexibility, and be requirements management oriented among other skills. Prior to gaining Advisors status, an individual needs experience designing systems which encompass numerous aspects including the open management system need for modifications, future integration of programs, and interface with other systems while ensuring requirements are met. Passing the certification examination is a must.

NMS Designer - The role must have top management commitment, unconditional resources, access to virtually all operational elements, be administratively oriented with skills to work with technical professionals and realize a software enterprise system has its limits in overall operational effectiveness. Employees must still understand work role interfaces and realize the communication dynamics mentioned above. Ideally, all employees understand they are quality professionals and systems thinkers / doers at some level during the course of each day.

The positions must be defined using standard roles and responsibilities (R/R) recognized by the industry. The R/Rs should be generic across all industries like those of a CPA, certified PMP, SHRM certified MR professional, and others. The most ideal management system advisors and designers must always be focused on assisting executives and the workforce to achieve Conformance to Requirements and hopefully strong systems thinkers.

“The need for Nuclear Management System Advisors and Designers is no different than the need for highly qualified Engineers and Designers for bridges, highways, schools, hospitals, refineries, ships, waste treatment facilities, and nuclear power plants. It takes an understanding of requirements while using a systematic approach.”

Nuclear Management System Course

The course is intended to offer participants a firm foundation in the design, development, implementation, and improvement of Nuclear Management Systems. It includes numerous concept models, visual aids, and discussion points that must be understood as the basis for designing and implementing an effective NMS.

Goals

- Concepts ~ learn concepts for application in nuclear management systems
- NMS Advisor | Designer ~ top management & attendees recognize this is a unique job role
- Philosophy ~ gain an understanding of U.S. thought leader philosophies on quality management
- Disciplines ~ understand the four quality professional disciplines
- Quality Tools ~ enhance understanding to ensure compliance, effectiveness, & efficiency
- Quality & The Law in Practice ~ understand implications & impacts of non-compliance
- Global Reach ~ promote a global generic basis for NMS framework, structure, methods, tools
- Collaboration ~ create quality continuity across the global industry including government entities

Objectives

- Implement multiple concepts relating to a compliant & effective NMS
- Ability to apply the four quality disciplines (QL, QM, QA, QC)
- Use NMS design approach to sustain an effective NMS
- Use Requirements & Information Management methods to ensure compliance & effectiveness
- Apply error prevention approach in the workplace & among the supply chain
- Apply understanding of interpretation needs for the “Shall” v. “Should” statements

Details

- Five-day classroom (lecture & workshop)
- Research & reading ~ course assignments
- Writing ~ course assignments
- Reading ~ follow-on recommendation list
- Subject Matter Experts (SMEs) ~ multiple concepts & instructors (GQM Advisors)
- Examination towards NMS Professional Certification ~ optional

The Need for NMS Advisor Certification

We are all aware of professional discipline-specific qualifications, credentials, registrations, and certifications mandated for certain job roles that emerged as needs arose. Design ~ licensed PEs, Accounting ~ CPAs, Program Management ~ PMPs, Quality Assessments ~ CLA (RAB, IRCA, ASQ), Human Resources ~ SHRM, and others.

Working in the capacity of an NMS Advisor | Designer must have a basis to demonstrate competence, especially considering the business risk and legal impact nature of the work. Leading and advising individuals in how the management system is designed and implemented to comply with the full spectrum of operating requirements brings considerable responsibility. Those who have NMS development and implementation experience, and thrive on system maintenance and improvement efforts, are prime candidates for gaining certification.

GQM Advisors initiated development of an intense course on **NMS Concepts | Requirements | Design | Systems Thinking | Integration | Compliance | Effectiveness**. Beginning in June 2016, a team of eight Advisors (collectively over 300 MYs), planned, researched, and began the course development effort. The mission was an internationally recognized NMS Advisor certification program with administration by the IAEA. We know that the need will soon be recognized and required in the nuclear industry. Those involved in our course will recognize the need. The inaugural course is planned for early 2019 hosted by the U.S. DOE at the Historic Virginian Hotel in Lynchburg, VA.

[A Partnership for Industry Improvement - GQM Advisors | IAEA | U.S. DOE | U.S. NEI | U.S. NRC](#)

It is with hope, the course will gain partnership with the U.S. Department of Energy and U.S. Nuclear Energy Institute. It is with hope, the U.S. NRC and the IAEA will recognize the course value for having informed industry executives.

[Author, Paul W. Gladieux, CEO | CQO | Researcher | Founder, Global Quality Management Advisors 1991](#)

Forty-five years of experience in all aspects of researching, advising, defining, designing, developing, deploying, and upgrading effective management systems focused on quality. Expertise foundation was gained in multiple sectors encompassing 14 system startups & 5 upgrades. **Founded GQM Associates 1991** to provide quality management system services to assist companies achieve system compliance and certification. The firm was a certified Small Woman-owned Business 2001 through 2016. **Re-focused GQM as Advisors in 2016** to provide companies with a broader range of expertise and offer of our knowledge using various methods with emphasis on the Next Generation. paul@gqmadvisors.com, www.gqmadvisors.com

Contributors

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