REVITALIZING QUALITY ASSURANCE

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Abstract

The image of someone inspecting or auditing often comes to mind when people hear the term quality assurance. Although partially correct, this image is not the complete picture. The person doing the inspecting or auditing is probably part of a traditional quality assurance organization, but that organization is only one aspect of a properly conceived and effectively implemented quality assurance system whose goal is improved facility safety and reliability.

This paper introduces the underlying philosophies and basic concepts of the International Atomic Energy Agency's new quality assurance initiative that began in 1991 as part of a broad Agency-wide program to enhance nuclear safety. The first product of that initiative was publication in 1996 of a new Quality Assurance Code 50-C/SG-Q and fourteen related Safety Guides. This new suite of documents provide the technical and philosophical foundation upon which Member States can base their quality assurance programs.

Just What is Quality Assurance?

When people hear the term "quality assurance," the image of an inspector or auditor often comes to mind. Although partially correct, the image evoked is incomplete. The inspector or auditor is probably part of a traditional, inspection-driven quality assurance organization, but that organization represents only one part of a properly conceived and effectively implemented quality assurance program.

In the broadest sense, quality is the degree of excellence that a product or service possesses. The degree of excellence required for any given product or service is determined by the customer's needs and is achieved by consistently anticipating and meeting his/her expectations. Quality assurance comprises all the actions, from product inception to application, that ensure the customer's needs and expectations are met.

A Short History

Quality assurance began with the first article made by man. Before there were factories, craftsmen depended on individual skill and knowledge to produce goods that served their intended functions. Skill and knowledge were passed from parent to child or from master to apprentice. The skills of some craftsmen were much better than those of others, and the quality of their work varied accordingly. Craftsmen prospered mainly on the basis of their reputations: the most skillful and creative could charge the highest prices for their products.

With the advent of mass production, the responsibility for quality shifted from the craftsman himself to the assembly-line foreman, who oversaw several workers as well as the production process. Under this system, the worker no longer controlled the product, its quality, or the process involved. Mass production thus marked a departure from the traditional value placed on individual achievement: based on acceptance of an average level of quality, the final product was better than that supplied by poor craftsmen but could not compare with that provided by the best. Moreover, the foreman was responsible for production quotas and shipping dates as well as quality. When deadlines drew near, choices often had to be made between business objectives and product quality. Given such choices, the quality of the final product was almost always compromised.

The "foreman-as-inspector" era lasted until World War II, when U.S. industry, of necessity, had to manufacture some of the largest and most sophisticated devices ever produced. The massive U.S. shipbuilding program provides but one illustration of how the system was inadequate. Quality-related problems became apparent when the production of ships for the U.S. Navy fell behind schedule. To speed up the process, the industry offered incentives to workers. Welders, for instance, were paid on the basis of how many feet of weld they completed or how many pounds of weld rod they consumed. As a result, production increased and the shipbuilding effort was soon back on schedule. However, during their first winter in the North Atlantic, tragedy struck when several new ships broke up and sank in relatively calm seas. A subsequent investigation determined that weld defects, resulting from material shortcomings and inadequate welding procedures, were the principal cause.

As a result of this investigation, one of the first modern programs to control quality was developed and implemented. The program identified the need to establish a formal quality assurance program, develop procedures, provide controls for materials, conduct inspections, perform tests, and take corrective actions throughout the construction process. This quality program was written into a basic quality control document and was later revised as U.S. Military Specification (MilSpec) Q-9858, which was issued in 1959. MilSpec Q-9858 probably represents the first systematic effort to ensure product quality in the post-World War II era. The premise behind this and other early programs was their reliance on an acceptable level of quality for any given component. Depending on the component, the probability that it would not be defective might range from 96 to 99 percent. This meant that a 1-4 percent failure rate could be tolerated. But when products became more complex, the 1-4 percent failure rate meant that the success of any given mission depended on luck. For example, if the product required 200 parts, 2-8 could be expected to fail. Success thus rested on the hope that the parts that failed were not critical to the mission.

During the late 1950's, when the U.S. space program was suffering its early setbacks, it became obvious that an improved system to control quality was necessary. The new system was based on the goal of mission success, not on individual component reliability. To achieve this goal, the National Aeronautics and Space Administration (NASA) responded with a program to identify critical components--and the new program used a performance-based approach. By definition, the failure of these critical components would endanger the mission. These critical components must demonstrate extremely high reliability, perhaps 99.99 percent or more, or would require backup in case of failure. To meet this extremely demanding reliability requirement, every step in the production process for each component would have to be verified.

As for the nuclear industry, in July 1967 the U.S. Atomic Energy Commission (AEC) published Appendix A ("General Design Criteria for Nuclear Power Plants") to Title 10, Part 50, of the Code of Federal Regulations (10 CFR 50). The first General Design Criteria in Appendix A contained only one sentence on quality assurance. It states simply that "a quality assurance program shall be established and implemented in order to provide adequate assurance that structures, systems, and components will satisfactorily perform their safety functions" as they relate to radiological safety.

During the licensing hearings for the Commonwealth Edison Company's Zion Plant in 1968, the AEC's Atomic Safety and Licensing Board criticized the industry's lack of standardized requirements for its quality assurance programs. The Board ruled that a document must be drafted to address these missing requirements. As a result, Appendix B ("Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants") of 10 CFR 50 was issued for comment in April 1969. In June 1970, Appendix B was approved and became part of the Code of Federal Regulations. The 18 criteria listed in Appendix B provided the basic requirements considered necessary for an acceptable quality assurance program and stressed the need for objective, documented evidence to prove that the quality of a facility was sufficient to justify the granting of an operating license. Appendix B refined several existing quality assurance programs, including MilSpec Q-9858 and the NASA program, and evolved them to a higher level. Its specific application was for commercial nuclear plant design, construction, and operation, but the program was applicable to modern industry in general.

What's Needed Now?

In many countries, including the United States, the nuclear industry has struggled for years to reestablish public confidence in its operations. Quality assurance is a tool that will help the industry meet this goal--not the traditional inspection-driven quality assurance, which has become the mainstay of the nuclear industry, but a more practical, holistic quality assurance system encompassing the work of every employee.

Quality assurance as it applies to the nuclear industry in particular is often misunderstood and misapplied. Over the years, many people representing diverse interests have written countless reports and papers supporting this conclusion. Quality assurance and the frustrations associated with it are the topics of conferences, meetings, and endless professional discussions. Real-life horror stories are shared about rogue auditors, belligerent plant managers, and the bureaucratic imposition of improperly or inadequately defined requirements. Serious action to change the status quo criticized by so many has now is now taking shape.

In 1996, as part of a broad, systematic program designed to enhance nuclear safety, the International Atomic Energy Agency (IAEA) issued a revised Quality Assurance Code 50-C/SG-Q and fourteen Safety Guides designed to improve the safety, reliability, and performance of Member States' nuclear facilities. The new Code and Safety Guides incorporate contemporary principles and techniques for managing, achieving, and assessing quality; they reflect modern principles and practices; and they make use of commonly accepted and understood concepts and terminology.

As a result, the nuclear industry has recognized that to be successful it must reach beyond traditional quality assurance methods. What this means is that management, workers, and those who assess the quality of work all contribute to plant safety, reliability, and performance. [1] Even though their respective roles differ, every employee (not just the quality assurance professional) implements the quality assurance program, ensuring that risks are minimized and that safety, reliability, and performance are maximized.

More and more, industry is looking to instill a "quality culture" where the customer's needs and expectations are met. The International Atomic Energy Agency's revised Quality Assurance Code 50-C/SG-Q and accompanying fourteen Safety Guides provide a platform from which to build such a culture, demanding an integrated team approach in which every employee works toward the shared goals of safety, reliability, and performance. No longer is the quality assurance professional alone on the front line trying to "inspect" quality into activities and processes over which someone else has control. In this new role, the quality professional focuses his/her attention on matters of substance rather than form.

The quality culture endorsed by the International Atomic Energy Agency recognizes that it is *management's* responsibility to establish and cultivate the principles that integrate quality into the daily work routine. For this integration to be successful, the people actually performing the work must receive appropriate information, tools, support, and encouragement. It is incumbent on management to define requirements clearly; properly train, motivate, and empower personnel; provide appropriate resources; and assess performance. Management should demonstrate commitment and leadership through active involvement in the implementation of an organization's quality assurance program. The individual employee's role is thus to meet established requirements and to recommend concurrent improvements in item and process quality.

As previously suggested, the concept of work (defined as any productive activity) is fundamental to a successful quality assurance program. From a task analysis point of view, all work can be broken down into fundamental building blocks. At the top of this hierarchy are performance objectives: these represent the reasons an organization exists; they define the goals to which the organization aspires. For the sake of clarity, performance objectives may be divided into intermediate objectives, which in turn are divided into subordinate objectives. The intermediate objectives describe the immediate steps or processes required to achieve the performance objectives, and the subordinate objectives provide the fine-grained details for how the

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[1] IAEA Quality Assurance Code 50-C/SG-Q defines the three functional areas of work responsibility as management, performance, and assessment.

intermediate objectives are to be accomplished. For the whole organization to work successfully, this hierarchy must be clearly defined by management and implemented by the line organization.

Performance objectives are achieved by means of implementing processes that are defined by the intermediate and subordinate objectives. When properly defined and controlled, these processes provide assurance that performance objectives will be met. The inherent interrelationship between performance objectives and processes defines an organization's level of success. When the balance between performance objectives and processes is skewed, when the organization's focus on the latter increases while the former is ignored, this crucial relationship is destroyed. The organization is no longer in a state of equilibrium. Internal controls fail. The ability of the organization to achieve its performance objectives--its reason for being--is lost. The organization itself ultimately fails.

The nuclear community often severs performance objectives from their processes. Many nuclear organizations become so engrossed in the "trees" of the processes (intermediate and subordinate objectives) that the "forest" of performance objectives is eclipsed from view. Traditional quality assurance programs focus on the fine-grained details of processes, not performance. Because organizations fail to identify and articulate their performance objectives, the credibility of the industry is called into question by a public that does not understand, and often fears, its objectives.

For example, a traditional quality assurance program for maintenance elevates the calibration of measuring and test equipment to the level of a performance objective rather than viewing it as one of a number of intermediate objectives.[2] Although the content of a traditional quality assurance program and a performance-based program are virtually the same, in the latter the intermediate objectives of calibration, control of items, work control, as well as subordinate objectives involving the use of instructions and procedures, are all recognized as supportive of the performance objective.

As illustrated by this example, a pragmatic performance-based quality assurance program strikes the appropriate balance between performance objectives and processes. In other words, it focuses on performance objectives without abandoning the processes needed to achieve them. The performance objectives of many organizations are buried two, three, or even four layers deep in the quality assurance program. Consequently, these programs lend themselves more readily to a process-dominated approach to quality assurance. A successful program is performance-based at the highest level. This biases the program toward achieving the whole organization's performance objectives, which should be carefully defined and limited in number.

Conclusion

The inherent limitations of traditional quality assurance have, in part, resulted in mediocre performance and have sometimes compromised plant safety, reliability, and performance. Many organizations have already begun implementing the principles described in the International Atomic Energy Agency's new Code and Safety Guides. Their successes attest to the common sense of implementing a more practical approach to quality assurance, one that emphasizes implementation, effectiveness, and results rather than program development and documentation.

Revitalizing quality assurance through the application of these principles requires constant willingness to reexamine and reevaluate the status quo. This in turn requires a willingness to accept and implement change. It is for the sake of improving plant safety and reliability that performance-based quality assurance programs using Code 50-C/SG-Q and the accompanying Safety Guides should be encouraged.

[2] The criteria listed in Quality Assurance Code 50-C/SG-Q combine performance, intermediate, and subordinate objectives into a comprehensive package of basic requirements. One of these criteria, "work processes," is the generic representation of such performance objectives as research and development, maintenance, software development and use, operations, and data collection.