Continuing Evolution of U.S. Nuclear Quality Assurance Principles, Practices and Requirements – PART I

August 2005

This document provides in two parts an accounting of the continuing evolution of quality assurance principles, practices and requirements for nuclear facility applications in the United States from 1954 to 2005.

EXECUTIVE SUMMARY[1].

PART I (this part) describes in SECTIONS 1 through V how nuclear quality assurance (NQA) and its documentation has evolved along four separate yet interrelated paths: (1) AEC>ERDA>DOE standards and directives; (2) AEC> NRC regulations and regulatory guides; (3) ANSI N45.2>ASME NQA-1 and related standards; and (4) ASME Section III Boiler and Pressure Vessel Code. It tracks the evolution of early AEC quality control and acceptance inspection requirements and practices for nuclear weapons production from the 1950s; the AEC quality assurance requirements for government-owned reactor and technology development programs from the 1960s; the AEC licensing regulations for designing, constructing and operating commercial nuclear power plants and fuel reprocessing plants from the 1970s; the development of ASME national consensus standards for nuclear facilities from the 1970s; the ASME code quality assurance criteria from the 1960s; and the management system and performance-based approach, also from the 1970s to date. SECTION VI outlines ASME NQA management issues. Section VII presents the ASME NQA Committee vision. PART I concludes with an attachment containing the basic NQA requirements of the ASME NQA-1-2004 Standard and an explanation of their implementation practices and benefits to be derived for the continuing assurance of quality in nuclear facilities.

PART II is a tutorial that discusses NQA terms and definitions; paradigm shifts from ineffectual NQA concepts; underlying principles of NQA-1 requirements; lessons learned for effective NQA programs; and a condensed chronology of events.

At the onset of nuclear power generation in the U.S., AEC regulators and nuclear utility owners were primarily concerned with assuring safe plant operation without due regard to formal management controls that were essential to ensure quality in achieving both safe and reliable operation of these complex facilities. Untoward problems during commercial nuclear facility design and construction phases eventually caused AEC regulators and nuclear utility plant owners to realize the importance and interrelationship of NQA to nuclear safety. Similarly, problems in AEC-owned reactor and test facilities led

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to the development of quality assurance standards and practices.

Early NQA activities were focused on the design of commercial nuclear power facilities. This focus then shifted to construction activities. Current emphasis is on the operations and maintenance of existing facilities.
Anticipating a revitalized U.S nuclear power plant industry and associated fuel reprocessing, design, construction and operation, the American Society of Mechanical Engineers (ASME) NQA Committee envisions in Section VII: (1) a broader adoption by the nuclear industry of ASME NQA-1 Standards: (2) a growing application of the Standards to DOE reactor and non-reactor nuclear facilities, and (3) a more timely endorsement by the NRC of successive versions of the Standards beyond 1994.

At the April 2004 meeting of the ASME NQA Main Committee approved Task Proposal Notice (TPN) enabling development of an historical and tutorial document on the origins, purpose and benefits to be derived from the principles, practices and requirements of quality assurance standards for nuclear facilities from 1954 to 2004. This document (PARTS I and II) is for information only and is not a part of the ASME NQA-1-2004 Standard.

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ACRONYMS

ACRS	Advisory Committee for Reactor Safety
AEC	Atomic Energy Commission
AL	Albuquerque Operations Office
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASLB	Atomic Safety and Licensing Board
ASME	American Society of Mechanical Engineers
B&PV	Boiler & Pressure Vessel
CFR	Code of Federal Regulation
CO	Compliance
CP	Construction Permit
CRD	Contractor Requirements Document
DOD	Department of Defense
DOE	Department of Energy
DNFSB	Defense Nuclear Facility Safety Board
DP	Defense Programs
DRL	Director of Reactor Licensing
DRS	Director of Reactor Standards
ERDA	Energy Research and Development Administration
FFTF	Fast Flux Test Facility
GOCO	Government-owned, contractor-operated
MWE	Megawatts electrical
NASA	National Aeronautics and Space Administration
NFPQT	Nuclear Facility Personnel Qualification and Training
NNSA	National Nuclear Security Administration
NQA	Nuclear Quality Assurance
NR	Naval Reactors
NRC	Nuclear Regulatory Commission
NSMB	Nuclear Standards Management Board
OGC	Office of General Counsel
OMB	Office of Management and Budget
PAAA	Price Anderson Amendments Act
QC	Quality control
RDT	Reactor Development and Technology
SNAP	Space Nuclear Auxiliary Power
SFO	Santa Fe Operations Office

PREFACE[2]

Nuclear quality assurance had its origin in the quality control and inspection practices of World War II. Quality control and inspection requirements were exercised through statistical process control techniques. These techniques were embedded in the early military and industrial products and nuclear weapons production standards. Quality assurance emerged as an adjunct engineering practice.

Early engineering efforts to design and construct components for nuclear power plants evolved through nuclear code cases arising from non-nuclear boiler and pressure vessel codes and standards. In 1963 and 1974, the first nuclear vessel codes emerged and became the foundation standard for extension to other pressure-retaining nuclear components rules. With the initial edition of the nuclear vessel code, Section III, the ASME provided a tutorial guide that was extremely helpful when orienting new people to the principles and practices underlying the rules and procedures that governed nuclear component design and fabrication. Later, as the body of experience and understanding grew and the nuclear component codes matured, this guidance was no longer essential and thus no longer promulgated.

In 1962, Vice Admiral Hyman G. Rickover [3], the recognized father of naval nuclear propulsion, spoke of a “cultural lag” in nuclear power plant management and manufacturing. He said industry practices were not geared to the higher standards imposed by the new power reactor technology. He laid out three principles for improving quality management:

1. More effective management and engineering attention must be given to routine and conventional aspects of nuclear power.

2. Specifications must be clearly understood, respected and enforced by manufacturers as well as customers.

3. More effective use must be made of quality assurance program requirements.

An exponential growth in the nuclear power plant market began in 1965. This growth followed the successful demonstration of commercial nuclear power at the Shippingport, Pennsylvania, nuclear plant. At that time, eight reactors with a combined capacity of 4870 megawatts electrical (Mwe) were on order. In the first eight months of 1966, 15 more reactors with a total capacity of 11,800 Mwe were ordered. By November 1966, there were 52 civilian power reactors with a total capacity of 26,890 Mwe on order. The AEC predicted an increase in capacity of from 80,000 to 110,000 total Mwe by 1980. Plant capacity had increased in size from several hundred to 1100 Mwe, including multiple units at some sites such as Commonwealth Edison’s Dresden station. Also, plants were being located in the proximity of largely populated metropolitan area.

This rapid growth in nuclear power plant orders and construction in the 1960’s eventually raised considerable concern among the members of the U.S. Congress, the AEC Commissioners and their inspectors, and senior utility industry officials. These concerns focused on the questions of:

> **Did the nuclear industry have sufficient numbers of skilled people to staff these very large and technically challenging projects without compromising the high quality standards necessary to protect public and worker safety? Conversely, did the AEC have sufficient staff to inspect, evaluate and oversee licensee applications and construction permits for nuclear power plants?**

AEC Commissioner James Ramey and RDT Director Milton Shaw spoke on numerous occasions about the need for quality assurance in nuclear reactor design and development projects and facility construction.

At a meeting of the American Nuclear Society in 1966, Commissioner Ramey[4] defined quality assurance as comprising:

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[2] Contributed by Joe Anderson, former ASME N45-2 Subcommittee Chairman and currently NQA Main Committee and Applications Subcommittee member.

[3] Address by VADM H.G. Rickover, “The Never-Ending Challenger”, 44th Annual Metals Congress, New York, NY, October 29, 1962.

[4] Address by AEC Commissioner James T. Ramey, “Quality Assurance as a Matter of Public Policy in the Safety 0f Atomic Power Plants”, 1966

"All actions necessary to provide adequate confidence that a product or facility will operate satisfactorily in service."

This definition was consistent with the DOD military specification[5] that defined quality assurance as[6]:

"A planned and systematic pattern of all activities necessary to provide adequate confidence that the item or product conforms to established technical requirements".

In 1968, Commissioner Ramey addressed the American Power Conference expressing his concerns about insufficiently experienced organizations causing errors and omissions resulting in startup problems and delays in nuclear power plant construction. He emphasized that these problems and delays demanded management leadership and urgent attention by the nuclear utilities.[7] He referred to his 1966 definition of quality assurance and the practices necessary for an effective quality assurance program.

Commissioner Ramey's concerns, when coupled with other unplanned events, led eventually to the development of AEC regulation on nuclear quality assurance, known as Appendix B to 10 CFR Part 50. In response to Appendix B, the ASME-sponsored American National Standards N45 Committee formed a quality assurance subcommittee to develop implementing quality assurance standards. This subcommittee subsequently became the ASME Nuclear Quality Assurance (NQA) Committee. Since their inception, these ASME standards have carefully preserved the early definition and the 0enlightened concepts of nuclear quality assurance.

Throughout the late 1960s and 1970s, as nuclear power plant construction projects continued to grow in size and numbers, groups of people were trained to conform to the ANSI N45.2 standards and later to the ASME NQA-1 standards. As we know now, the nuclear industry designed, constructed and successfully operated over 100 nuclear power plants; however, no new plants have been ordered for over 20 years. During this time, many of the skilled workers in the US nuclear industry who managed, designed and constructed these plants have moved to other careers, retired, or are nearing retirement. The nuclear industry may again be approaching the same situation it initially faced in the early 1960's: a lack of knowledgeable and skilled management, technical and quality assurance professionals.. There has been a tremendous amount of accumulated experience and best practices have been developed, documented and codified over the past 50 years. This knowledge must not be lost to the future designers, constructors and operators of nuclear power generation facilities.

With the prospect emerging again for new nuclear power plant orders and a new cycle of growth in the nuclear power industry, the ASME NQA Committee believes it is appropriate and timely to prepare an historical record of events (PART I) and tutorial (PART II)as guidance for the next generation of managers, technical specialists and nuclear quality assurance professionals. The ASME NQA Committee intends that this publication will be publicly available on the ASME website and used to acquaint newly involved management, technical and quality assurance professional with the "what", "how" and "why" of the principles, practices and requirements that have been defined and documented in ASME NQA-1 and other standards, as well as with some of the key quality management issues.

TIMELINE

The following chronology traces significant events and reactions in the evolution of AEC, ERDA, DOE, ASME and other related NQA standards and directives from 1954 to 2004:

Winter Meeting of the American Nuclear Society, Pittsburgh, PA, November 2, 1966.

[5] MIL-STD-109, Quality Assurance Terms and Definitions, (Source: MIL-STD-490. SPECIFICATION PRACTICES, 30 October 1968)

[6] Reference to MIL-STD-109 definition of quality assurance contributed by Robert Hartstern, member, ASME Nuclear Quality Assurance Committee.

[7] Address by AEC Commissioner James T. Ramey, Quality Assurance – An Essential for Safe and Economic Nuclear Power", American Power Conference, Chicago, IL, April 23, 1968.

- **1954:** The Atomic Energy Act of 1954 amended the Atomic Energy Act of 1946, defined the AEC function, and established the AEC in Germantown, Maryland, and Washington, D.C., in 1957, encompassing both regulatory and developmental functions.

- **1954:** AEC Santa Fe Operation Office issued QC-1, Weapons Quality Policy, prescribing nuclear weapons production quality control and inspection practices.

- **1956**: Dresden 1 and Indian Point 1 received the first AEC construction permits (CP) under Title 10, Code of Federal Regulation, Part 50, with no specified quality assurance program criteria or requirements.

- **1963:** ASME issued Section III of the Boiler and Pressure Vessel (B&PV) Code with no specified quality assurance requirements.

- **1965-1967:** AEC developed a proposed Appendix A to 10 CFR Part 50 covering nuclear power plant design criteria. Criterion 1, Quality Standards and Records, required (1) quality standards, (2) a quality assurance program and (3) quality records for structures, systems and components important to safety.

- **1966:** Fermi 1 incident resulted from unauthorized design changes causing partial reactor core meltdown. Also, AEC reported ten reactors that were in operation for approximately 2 ½ years, were then closed.

- **1967:** During Turkey Points 3 & 4 CP review, the ACRS asked about but did not pursue “methods of quality control”.

- **1967:** ASME published Section III, Appendix IX, of the B&PV Code containing 15 quality assurance criteria and requiring ASME review and approval.

- **1967:** Brown’s Ferry 1 and 2 CP review found a lesser commitment to quality assurance. ACRS was concerned because these were the first reactors to exceed 1000 Mwe.

- **1967:** The AEC regulatory function moved to Bethesda, MD, while the development function stayed in Germantown, MD.

- **1968:** The Atomic Safety and Licensing Board (ASLB) suspended public hearings on a Commonwealth Edison’s application to design and construct a nuclear power plant because (1) the license applicant did not have a quality assurance program for the plant and (2) the AEC did not have criteria for evaluating the adequacy of the applicant’s quality assurance program

- **1969:** The AEC Reactor Development and Technology (RDT) Division developed and issued a comprehensive quality assurance program standard, RDT F2-2T, for its government-owned and contractor-operated (GOCO) reactors and test facilities.

- **1969:** AEC regulatory function proposed for public comment 18 quality assurance criteria as Appendix B to 10 CFR Part 50 for licensing nuclear power plants,

- **1969:** Representatives of the AEC and the nuclear industry met to begin developing N45.2 standards on quality assurance program requirements and guidance for nuclear power plants.

- **1970:** Following an extensive pubic comment period and a trial use at Surry, the AEC issued 18 quality assurance criteria for nuclear power plants as Appendix B to 10 CFR 50, thereby expanding upon Criterion 1 of Appendix A to 10 CFR 50.

- **1971:** AEC issued Appendix A of 10 CFR 50.

- **1971:** AEC expanded Appendix B of 10 CFR 50 to apply the 18 quality assurance criteria to fuel reprocessing plants as well as to nuclear power plants.

- **1971:** The American National Standard (ANSI) N45-2-1971, was issued.

Supplementary N45.2 (daughter) standards were issued in subsequent years.

- **1972:** American Nuclear Society (ANS) published ANS 3.2-1972 standard for administrative controls during nuclear power plant operation.

- **1974:** The Energy Reorganization Act of 1974 abolished the AEC and established separate agencies in the Nuclear Regulatory Commission (NRC) and the Energy Research and Development Administration (ERDA).

- **1974**: Due to some organizational issues at LaSalle and Midland, the AEC>NRC proposed an amendment to Criterion I, Organization, of 10 CFR Appendix B with regard to permissible organizational relationships; Criterion 1 amendment was approved and issued early in 1975.

- **1975:** ASME established the ASME Committee on Nuclear Quality Assurance (NQA) to continue developing, coordinating, and consolidating and restructuring nuclear quality assurance standards.

- **1975**: Browns Ferry fire occurred.

- **1977:** ASME NQA Committee issued ANSI/ASME N45.2-1977 on quality assurance program requirements for nuclear facilities.

- **1977**: ERDA was abolished with the creation of the U.S. Department of Energy.

- **1978:** ANSI N46-2 Committee issued Revision 1 of its ANSI N46.2-1978 standard for Post-Reactor Nuclear Fuel Cycle Facilities, which was subsequently withdrawn.

- **1979:** Three Mile Island Unit 2 suffered severe operational casualty due to minor maintenance errors and a stuck pressure-relief valve leading to a loss of crew operational awareness and resulting in major core damage.

- **1979:** ASME NQA Committee issued ASME NQA-1-1979 on quality assurance requirement for nuclear facilities

- **1981:** DOE issued Order 5700.6, Quality Assurance, in response to deficiencies observed by the DOE Inspector General in DOE nuclear facilities. This Order was superseded by DOE Orders 5700.6A, in 1981, 5700.6B in 1986 and 5700.6C in 1991, which was superseded by DOE Order 414.1 in 1998'

- **1983:** ASME NQA Committee issued ASME NQA-1-1983.

- **1983:** ASME B&PV Code Section III, Appendix IX, adopted ASME NQA-1-1983 edition with addenda through 1992.

- **1983:** ASME NQA Committee incorporated seven NQA-2 quality assurance standards as parts of ASME NQA-2-1983.

- **1985:** NRC endorsed ASME NQA-1-1983 in Revision 3 of Regulatory Guide 1.28.

- **1986:** ASME NQA Committee issued ASME NQA-1-1986 with minor editorial changes to the 1983 edition, with several positions.

- **1989:** ASME NQA committee issued ASME NQA-1-1989 on quality assurance requirements for nuclear facilities.

- **1989:** NRC move to amend 10 CFR50 Appendix B to address counterfeit and fraudulent parts was unsuccessful.

- **1991:** NRC endorsed ASME NQA-1 and NQA-2 in NRC Standard Review Plan 17.3.

- **1991:** DOE published a proposed Nuclear Safety Management Rule under 10 CFR Part 830 and subpart 830.120 on quality assurance; DOE also issued DOE Order 5700.6C, Quality Assurance, introducing ten performance-based quality assurance criteria including the concept of quality improvement. These ten criteria were used in the proposed Rule.

- **1994:** DOE published the Nuclear Safety Management Rule, 10 CFR Part 830 and subpart 830.120. The Rule provides for civil and criminal penalties similar to the NRC rules for commercial nuclear facilities.

- **1994:** ASME NQA Committee issued the ASME NQA-1-1994 edition, quality assurance requirements for nuclear facility applications.

- **1997:** ASME NQA Committee issued the ASME NQA-1-1997 edition with continued restructuring and removal of redundant text.

- **1998:** DOE Order 414.1, issued in November 1998, was superseded by DOE Order 414.1A in May 1999, by DOE Order 414.1B in April 2004.

- **2000**: ASME NQA Committee issued ASME NQA-1-2000 with minor revisions to the 1997 edition.

- **2001:**DOE revised the Nuclear Safety Management Rule to include Safety Basis requirements and minor changes to the quality assurance Rule, clarifying its applicability to nuclear weapons and radiological facilities.

- **2004:** ASME NQA Committee issued ASME NQA-1-2004 containing numerous revisions to the 2000 edition.

- **2004:** DOE/NNSA issued Revision 10 of QC-1 on DOE weapons quality policy.

- **2005:** DOE Order 414.1C, Quality Assurance, supersedes DOE Order 414.1B

- **2005:** DOE published Action Plan based on lessons learned from the Columbia Space Shuttle accident and Davi-Besse reactor pressure vessel head corrosion event.

SECTION I.

AEC/ DOE QUALITY ASSURANCE REQUIREMENTS AND RULES

This section describes the evolution of nuclear quality assurance from early quality control and inspection requirements for AEC nuclear weapons production and Naval Reactors programs; to the more comprehensive quality assurance program requirements for nuclear weapons production and AEC/DOE reactor development and technology activities; and to the series of DOE quality assurance directives.

AEC Weapons Quality Policy (QC-1)

AEC quality management policy for nuclear weapons complex activities was first documented in the former AEC Santa Fe Operations (SFO) Weapons Quality Policy (QC-1). Issued in April 1954, QC-1 pre-dated MIL-Q-9858A [8], which was issued in 1959 and widely the used Department of Defense (DOD) specification for military quality assurance programs.

The initial QC-1 quality control and inspection principals and requirements included:

- Specification and drawing control
- Quality control procedures
- Control of inspection gauging and test equipment
- Production tooling accuracy
- In-process inspection and records
- Control of special processes
- SFO/DOE source inspection
- Raw material and deviation control

QC-1 prescribed general principles and practices for AEC-SFO acceptance inspection of nuclear weapons systems and auxiliary equipment from prime contractors. It required weapons program prime contractors to establish and implement quality control systems to assure, among other things, that nuclear weapons materials met minimum quality standards. SFO expected these principles and requirements to be applied also to ordnance plants operated by the DOD on the behalf of SFO and to arsenals that performed work for the SFO under agreements with DOD.

In 1982[9] and again in 1989[10], the DOE Assistant Secretary for Military Applications defined and redefined in greater detail the quality assurance policy for the DOE nuclear weapons complex. This policy required the execution and maintenance of procedures that:

1) Provided control, through pans and actions, over activities affecting quality to an extent consistent with defined programmatic or organizational objectives;

2) Had objective, measurable means to assure its effectiveness, which shall be used by management for regular assessments;

3) Emphasized continuous improvement in all activities including support as well as operational organizations; and

4) Applied appropriate elements of recognized standards.

QC-1 has been revised numerous times from its initial issue in 1954 to its most recent issue in 2004 to address changes and additional DOE weapons quality policy and quality assurance requirements. Thus, for example, Revision 6, issued in 1992, added quality system requirements for training of manufacturing, inspection and test personnel, for quality improvement, for error prevention versus detection, and for nonconformance costs.

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[8] Department of Defense (DOD) Military Specification MIL-Q 9858[8], Quality Program Requirements, issued in April 1959, superseded by MIL-Q-9858A in December 1963.

[9] Depart of Energy Assistant Secretary for Military Applications, Quality Assurance Policy, July 7, 1989.

[10] Depart of Energy Assistant Secretary for Military Applications, Quality Assurance Policy, November 20, 1989.

The highly classified nature of most DOE Defense Program (DP) weapons production activities governed by QC-1 led to some external criticism that DP lacked a viable quality assurance effort that complied with DOE quality assurance directives. DP quality management policy in the 1980s exempted DOE nuclear weapons program from complying with Departmental quality assurance Orders on the basis of equivalency. Then, in 1992, in a memorandum to DOE field office managers[11], the Assistant Secretary for Defense Programs declared that DP would comply with DOE Order 5700.6C, discussed below, with certain exemptions for classified weapons-production work. The Assistant Secretary decided that it would be to DP's advantage to be able to demonstrate to oversight organizations, e.g., Congress, NRC, EPA and various public interest groups that DP did in fact have a systematic, disciplined quality assurance program for its weapons production activities.

In 1992, the DOE Albuquerque Operations Office (AL) issued a new standard, QC-2, to complement QC-1 for nuclear weapons research, development and testing. Revision 9 of QC-1, issued in late 1998, incorporated QC-1 as well as newer quality assurance requirements of QC-2 for nuclear weapons research, design, development, procurement, production, dismantlement, maintenance, stockpile evaluation and disassembly/disposal.

From its inception in 1954 to the current 2004 revision, QC-1 policy, principles and requirements have placed maximum responsibility and accountability:

- On nuclear weapons program prime contractors to maintain effective quality control systems;
- On the AEC/DOE to conduct surveillance and acceptance inspections that focus on functional quality evidence presented by the prime contractors; and
- On AEC/DOE for verification of this quality evidence.

[11] DOE Defense Programs Memorandum, Implementation of Department of Energy Order 5700.6C, "Quality Assurance", February 27, 1992.

In February 2004, the DOE/National Nuclear Security Administration (NNSA) issued Revision 10 of QC-1[12], superseding Revision 9. Revision 10 of QC-1 contains the following significant changes for that organization that must comply with DOE weapons quality policy:

- Change of ownership from AL to DOE/ DOE/National Nuclear Security Administration (NNSA) Headquarters DP
- New requirement for a management program (QAP) or WQAP to be submitted to DOE/NNSA for approval
- Major emphasis on a risk-based quality management system for decision making
- Grater emphasis on quality metrics

Revision 10 of QC-1 has been restructured along the lines of NQA-1-2000 to ensure that QC-1 could be implemented using the NQA-1 standard. DOE/NNSA expanded the scope to include weapons work conducted by the federal organization and the management controls beyond hardware QC. Another major change made it clear that QC-1 is the DOE/NNSA method for implementing DOE Order 414.1A and the DOE Nuclear Safety Management Rule, 10 CFR 830 Subpart A (discussed below). All federal and contractor work relating to nuclear weapons is now covered by the DOE/NNSA quality assurance Order, Rule and contract direction.

While Revision 10 of QC-1 adopts a number of NQA-1 requirements, there are some differences. For example, QC-1 establishes a two-party GOCO contractual relationship. Also QC-1 includes the following additional quality assurance requirements:

1.11	Metrics
1.11.1	Quality Cost Management
1.12	Control of Processes
3.8.1	Process Control Methods
1.12.1	Government Furnished Material
1.12.2	NNSA Accepted Material
1.13	Senior Management Responsibilities

<u>AEC Naval Reactors QRC-82C</u>

[12] DOE/NNSA Weapons Quality Policy (QC-1), 02/10/2004

Quality control (QC) requirements for AEC naval nuclear propulsion programs were prescribed in the AEC document QRC-82C[13]. This document supplemented MIL-Q-9858A by imposing QC requirements for material inspection and testing during manufacturing of naval reactor (NR) components.

AEC>DOE RDT F2-2T Standard

From its beginning, the AEC managed and operated its civilian reactor and technology development programs as a decentralized agency. AEC Headquarters developed policy, managed funding and issued broad programmatic direction to its field organizations. The AEC issued grants to universities, national laboratories and research and development contractors.

Notwithstanding the good operational safety records in the late 1960s, AEC Reactor Development and Technology (RDT) management and engineers were disturbed to note that important civilian reactor and technology development objective were not being accomplished as planned. Quality problems, including equipment failures and irretrievable loss of important data, were attributed not to the inherent risks of technology development but to insufficient management and engineering attention to conventional material and process controls. Fundamental, exacting engineering standards and quality controls that were essential to technology development were not being applied.

Some early AEC, DOE and contractor project management misconceptions about quality assurance were :

- Some project managers believed it was possible to assure nuclear facility quality without a formal, documented and integrated quality assurance program. While this approach was used for small basic research reactors, quality-related operating problems resulted in shutting down production reactors at most DOE sites and prevented their restart.
- Some project managers believed that the quality assurance program establishment and implementation was the primary responsibility and role of the quality assurance organization. This misconception was fostered in part by some quality assurance organizations that believed that the quality assurance plans, requirements and procedures were written by and for the quality assurance organization. They failed to recognize a fundamental quality assurance principle:

> **Quality and its achievement is a primary management responsibility; the quality assurance organization supports top and line management in executing their quality assurance programs and by conducting independent audits.**

Prior to 1968, there were no formal quality assurance requirements imposed by the AEC and its management and operating contractors on GOCO nuclear facilities conducting reactor development and technology activities. This situation presented an early quality management dichotomy for the National Aeronautical and Space Administration (NASA) quality engineers who had technical and quality management oversight of some joint NASA/AEC space exploration programs. For example, in the mid-1960s, NASA's Space Nuclear Auxiliary Power (SNAP) Programs imposed rigorous quality assurance and quality control requirements from the NASA quality program standards [14]on some of its prime contractors, e.g., Aerojet General in Azusa, California, and General Electric in Evendale, Ohio, to name a few. NASA delegated to DOD Air Force, Navy and other contract administration agencies certain DOD inspection system requirements[15] for non-nuclear, non-mission-critical components of the power conversion system being developed by the contractor. NASA quality assurance program managers were disappointed to learn that the AEC did not impose any formal quality assurance

[13] AEC QRC-82C, Quality Program Requirements, June 7, 1964.

[14] NASA NHB 5300.4(1B), Quality Program Provision for Aeronautical and Space System Contractors, April 1969 Edition (formerly NPC 200.2, April 1962.

[15] MIL-I-45208A, Military Specification, Inspection System Requirement. 16 December 1963

or/quality control requirements on the SNAP reactor-system-development contractors. The NASA Lewis Associate Director brought this situation to the attention of the joint AEC-NASA organization.

In mid-1968, the AEC Division of Reactor Development and Technology (RDT) senior managers acknowledged the need for a comprehensive quality assurance program standard that could be imposed on GOCO reactors, technology development programs, national laboratories and test facilities[16]. RDT management agreed to develop the new RDT standard that would be designed to address not only the quality program and inspection system specifications of MIL-Q-9858A and MIL-I45208A but also the more comprehensive quality and reliability assurance program requirements of the NASA publication NHB 5300.4(1B). The proposed standard would provide for planning, management and engineering activities as well as additional requirements for design review, design verification testing, qualification testing and development testing.

It is noteworthy that Admiral Rickover's AEC Naval Reactors programs employed some of these design control elements as a part of their normal design engineering activities, although they were not called quality assurance elements. So it was not too difficult to convince the RDT line managers who came from Naval Reactors that design control was still their line responsibility under the broad quality assurance umbrella.

With the participation of the major AEC national laboratories and M&O contractors, RDT Director Milton Shaw authorized in late 1968 a working group, managed by the author, to develop the new standard. RDT F2-2T was issued in June 1969 under the RDT standards program managed by the Oak Ridge National Laboratory (currently managed by the DOE Office of Environment, Safety and Health).

RDT F2-2T was written in a phased format to be selectively applied to a facility or project that flowed from initial quality assurance program planning, through design and development; procurement; manufacturing, fabrication and assembly; construction and installation; to facility operation, maintenance and modification, depending on scope of the quality assurance program activities.
RDT F2-2T covered all of the basic quality assurance criteria of 10CFR50 Appendix B. Also included were quality assurance program requirements for design descriptions, development testing, engineering studies, operational readiness reviews, unusual occurrence reporting, data collection methods, material certification, alloy verification, and management reviews. Many of these RDT F2-2 quality assurance requirements had been proven to be effective in earlier NASA flight system and ground support operations.

RDT F2-2T was a dynamic standard that was fully endorsed and used by RDT technical and quality assurance managers. At the request of RDT managers, RDT F 2-2T was amended ten times from 1969 to 1983, to improve the effectiveness quality assurance program implementation based on user experience and on unusual occurrences reporting during design, construction and operation of AEC/DOE numerous reactors and test facilities. These amendments included:

1. Purchaser approval of repairs and waivers

2. Planning and documentation of independent design reviews

3. Surveillance of facility operations, maintenance, modifications and repairs

4. Preparation of engineering drawing lists.

5. Purchaser approval of inspection and test plans and establishment of mandatory hold points

6. Control of handling, lifting and rigging activities

7. Selective application of quality assurance requirements and preparation of a quality assurance program index of procedures

8. Calibration and control of measuring and test equipment

[16] Address by Merritt E. Langston, "Quality Assurance Requirements for Reactor Development Programs", 26th Annual Technical Conference of the American Society for Quality Control, Washington, D.C, May 10, 1972.

9. Indoctrination, training and qualification of personnel

10. Identification, reporting and management of engineering holds

In a large construction project, e.g., the Fast Flux Test Facility (FFTF), special quality assurance requirements and controls were incorporated through these amendments to RDT F2-2T. The amended requirements helped to detect, eliminate, or prevent the installation or use of improperly identified and mixed weld filler metal and many other substandard materials purchased for FFTF construction.

Amendment 6 resulted from a rash of handling, lifting and rigging incidents at DOE facilities. RDT also developed a stringent RDT F 15.2 standard on testing and lifting controls, particularly over reactors.

Amendment 7 to RDT F2-2T abolished costly and voluminous quality assurance program descriptions that merely repeated the contents of implementing procedures. Instead, users were instructed to prepare a quality assurance program index including the organization structure and a listing of quality assurance procedures.

In his memorandum of March 1972 to RDT technical professionals, RDT Director Milt Shaw called their attention to the promulgation of RDT F2-2T, which reinforced the many policy statements and related actions of the Congress, the Commission, the ACRS, and standards-writing groups over several years on the need to significantly strengthen quality assurance in conducting reactor and technology development programs, whether in the national laboratories or in the commercial sector.

In a 1978 memorandum to DOE field office managers[17], the DOE Director for Nuclear Energy stated that DOE preferred the quality assurance program for civilian nuclear energy technology development programs to be established and implemented in accordance with applicable requirements of the nationally recognized, voluntary consensus standards. Unless otherwise directed, or where there was no cost advantage, major DOE reactor development program were to employ the N45.2 standard. Where N45.2 was determined to be insufficient for technology development activities, it was to be supplemented by appropriate quality assurance requirements.

Acting on the recommendation of an RDT study group under Dan Garland to endorse a single national consensus standard for reactor and technology development programs, in April 1985, RDT management canceled and withdrew the RDT F2-2 standard when it endorsed the ANSI/ASME NQA-1-1983 standard. The shift to the NQA-1 national consensus standard was consistent with an Office of Management and Budget (OMB) Circular A-119 regarding the use of such national consensus standards.

A comparison of the RDT F2-2 standard with ANSI/ASME NQA-1-1983 revealed consistencies in their basic quality assurance program elements but significant differences in their degree of specificity, particularly when applied to reactor development and testing activities, and in their format.

By endorsing the NQA -1-1983 standard, RDT relinquished its technical and quality management ability to make rapid, timely and substantive changes to quality assurance program requirements based on urgent needs back by field experience. The ASME NQA-1 consensus process achieved thorough reviews of draft standards but did not lend itself to the processing of rapid, program-specific changes.

<u>DOE Order 5700.6</u>

In March 1978, the DOE Inspector General (IG) advised DOE Headquarters senior managers that IG inspectors were observing major continuing deficiencies in formal quality assurance programs at DOE field sites. These deficiencies included:

- Inadequate or nonexistent quality standards;
- Inadequate design control and design reviews;

[17] Assistant Secretary for Energy Technology, Director of Nuclear Energy, Quality Assurance Policy for Nuclear Energy Program, 9-1-78

- Inadequate supplier controls; and
- Inadequate fabrication controls.

These deficiencies were attributed in part to the lack of a strong DOE Headquarters quality assurance policy, organization and implementing requirements. For many years, the AEC and DOE national laboratories and contractors had operated under a system of grants for research and development that only required periodic progress reports on activities and how funds were being spent. The AEC requested but did not direct quality assurance compliance

In response to the IG advisory, in 1979 the DOE Secretary of Energy appointed a study group headed by Phil Coyle of DP, including the author, to develop recommendations on a Department-wide quality assurance policy and requirements. In January 1981, with the concurrence of the DOE Secretary of Energy, DOE Order 5700.6[18], Quality Assurance, was issued.

The DOE Nuclear Facility Personnel Qualification and Training Committee (NFPQT), which was appointed by the Under Secretary of Energy after the accident at Three Mile Island in 1979, reported that the DOE quality assurance Order was being implemented in varying degrees of rigor at most DOE nuclear facility sites.

> ***The NFPQT reported that a common deficiency was the lack of management controls and attention paid by senior DOE and contractor managers to implementing effective quality assurance requirements at DOE nuclear facility sites.***

As a result of the NFPQT report, the DOE Under Secretary of Energy developed a DOE Action Plan. A revised DOE Order 5700.6A was issued in an attempt to strengthen the Department's dysfunctional quality assurance policy. In September 1986, DOE Order 5700.6B only addressed changes in DOE Headquarters responsibility for quality assurance oversight.

DOE Order 5700.6C[19]

In August 1991, a completely restructured DOE quality assurance Order, 5700.6C, was published as a part of a comprehensive DOE directives system. This system includes DOE Policies, Manuals, Orders, Notices, Regulatory Rules and Guides for quality assurance plus a variety of many other subjects, which may be accessed though the DOE Internet at http://www.directives.doe.gov. Information specific to the Department's quality assurance policy is available at http://www.directives.eh.doe.gov/qa.

DOE 5700.6C established Total Quality Management arrangement of DOE quality assurance program requirements into three categories and ten criteria, as follows:

- **Management**

1. Program
2. Personnel Training and Qualification
3. Quality Improvement
4. Documents and Records

- **Performance**

5. Work Processes
6. Design
7. Procurement
8. Inspection and Acceptance Testing

- **Assessment**

9. Management Assessment
10. Independent Assessment

> **DOE Order 5700.6C reflected the concept that all work is a process that can be**

[18] U.S. Department of Energy Order, DOE 5700.6, Quality Assurance, 1-16-81.

[19] U.S. Department of Energy Order, DOE 5700.6C, Quality Assurance,8-21-91.

managed, performed, assessed, and improved, i.e., by adopting a management system approach to quality.

The ten basic criteria of DOE Order 5700.6C provided general quality assurance requirements for all work to be performed by DOE and its contractors. The 10 criteria were stated as expected outcomes (performance-based), rather that as prescriptive “how to” requirements. The Order also included definitive responsibilities for federal managers in their oversight roles.

The quality assurance criteria were fairly well understood by DOE and contractor organizations. However, Criterion 3, Quality Improvement, Criteria 9, Management Assessment, and Criterion 10, Independent Assessment, posed a challenge to organizations unfamiliar with contemporary quality concepts. So, DOE developed an implementation guide for DOE Order 5700.6C to illustrate the management system concept for quality; expand on the performance-based criteria; and define acceptable approaches to implementing the Quality Improvement, Management Assessment and Independent Assessment criteria.

DOE Order 5700.6C referenced ASME NQA-1, ASME NQA-2, ASME NQA-3 and a number of DOE and other standards.

Exempted from DOE Order 5700.6C was work associated with DOE nuclear weapons production, Naval Nuclear Propulsion Programs, NRC licensing, and research and development (R&D) publications. This Order did not exempt work associated with design construction, operation, and maintenance of facilities and equipment used to produce nuclear weapons.

DOE 5700.6C required the use of appropriate standards, such as ASME NQA-1 (discussed below) to develop and implement quality assurance programs. The Order stressed the following three quality management principles:

1. Senior DOE and contractor managers are responsible for quality assurance program management, implementation, assessment, and improvement;
2. Line organizations achieve quality; and
3. Overall performance is measured and evaluated using a rigorous assessment process.

The following 12 underlying principles and actions were the basis for the DOE 5700.6C performance-oriented quality assurance criteria:

1. Define policies and objectives – ensure they are understood and accepted.
2. Specify roles and responsibilities – ensure they are understood and accepted.
3. Specify and communicate expectations – identify and allocate resources to achieve them.
4. Strive to continually improve quality objectives.
5. Ensure people are competent at the work they perform.
6. Ensure the right people have the right information at the right time.
7. Seek and use relevant experience.
8. Plan and control work.
9. Use the correct materials, tools and processes – control changes to them.
10. Assess work results to ensure it meets what is required and exceeds customer expectations.
11. Identify and remedy errors and deficiencies.
12. Periodically review management processes to improve their effectiveness and efficiency.

Whereas previous DOE quality assurance directives were applied only to contractors, DOE Order 5700.6C required both the DOE and contractor organizational elements to develop and implement quality assurance programs that complied with the ten criteria.

Attachment 1 to DOE Order 5700.6C provided guidance for developing and implementing quality assurance programs to satisfy the ten quality assurance criteria. DOE national laboratories and contractors were required to prepare and submit for DOE evaluation and approval a Quality Assurance Program to describe how each organization would comply with the applicable criteria of DOE Order 5700.6C. Where an organization was not in compliance, an Implementation Plan was required to describe the actions and schedules for achieving compliance.

DOE Orders 414.1 and 414.1A [20]

In November 1998, DOE issued a new draft quality assurance directive, DOE Order 414.1[21], for review and comment. The new Order superseded DOE Order 5700.6C. It redefined the scope in conjunction with the new DOE Nuclear Safety Management Rule 10 CFR 830 and subparts 830.120 and 122 on quality assurance discussed below. The Order applied to both DOE and contractor organizations.

DOE Orders 414.1 and Revision 414.1A[22] were developed in coordination with the DOE-chartered Quality Assurance Topical Standards Committee (QA TOPCOM) and the Quality and Safety Management Special Interest Group (QSMSIG). These committees provided an avenue for Gustave (Bud) Danielson, the DOE Quality Policy Manager, to gather broad input from national/international standards bodies, standards users and users of the Order and Guides; Danielson charted these committees, which were composed of representatives of DOE, national laboratories, and contractors with expertise in quality assurance, assessments and management. The QM/SIG has since been disbanded.

Attachment 1 of DOE Order 414.1A was a contractor requirements document (CRD) that included all of the general quality assurance requirements and the ten quality assurance criteria. For example, the CRD required submittal of a contractor's quality assurance program document to a designated DOE official for approval. The CRD was developed by DOE for attachment to all of its Orders and is intended to be a stand-alone document suitable for use directly in a contract. As such, it does not include section from the Order that only apply to federal organizations (e.g., DOE Headquarters and field office responsibilities.)

Attachment 2 of DOE Order 414.1A contained supplemental quality improvement requirements for corrective action plans for significant safety issues resulting from DOE Office of Oversight reports and other issues as specified by the Secretary of Energy. This new Corrective Action Management Program was developed in response to the Defense Nuclear Facilities Safety Board (DNFSB) Recommendation 98-1.

General guidance on implementation of DOE Order 414.1A was published in DOE G 414.1-2. This superseded the original guidance in Attachment I to DOE Order 5700.6C.

DOE Order 414.1B[23]

DOE Order 414.1B supersedes DOE O 414.1A. Its purpose is to ensure that DOE National Nuclear Security Administration (NNSA) products and services meet or exceed customer expectations. This objective is to be achieved based on the following principles:

1. Quality is assured and maintained by a single, integrated, effective quality assurance program, i.e., a management system;
2. Management support for planning, organization, resources, direction and control are essential to quality assurance;
3. Performance and quality improvement require thorough, rigorous assessment and corrective action;
4. Workers are responsible for achieving and maintaining quality; and

20 The remainder of this section on DOE Orders , Rules and guides was contributed by Bud Danielson, ASME NQA Main Committee member; and Chairman, NQA Subcommittee on Applications.

21 U.S. Department of Energy Order 414.1, Quality Assurance, 11-24-98

22 U.S. Department of Energy Order 414.1A, Quality Assurance, 5-19-99.

23 U.S. Department of Energy Order 414.1B, Quality Assurance, 4-29-04.

5. Environmental, safety and health risks and impacts associated with work processes can be minimized while maintaining reliability and performance of work product.

DOE Order 414.1B requirements applied to NNSA and contractor organizations, except for the exclusion of NNSA Naval Reactor Programs. The Order referenced ASME NQA-1-2000 for nuclear-related activities and ANSI/ASQ Q 9001:2000 for non-nuclear activities. Thus, a DOE contractor's quality assurance program was (and is still) expected to use the appropriate American national or international consensus standard, where practicable and consistent with contractual and regulatory requirements. Attachments 1and 2 contained essentially the same ten basic quality assurance criteria taken from the superseded DOE Orders 5700.6C and 414.1A for DOE and contractor organizations, respectively; Attachment 3 describes the DOE-wide process for controlling suspect/counterfeit items (S/CI). The Order updated S/CI requirements based on field experience and was supported by a new guide, DOE G 414.1-3 [24] for controlling suspect/counterfeit items.

DOE Rule 10 CFR Part 830

The Price Anderson Amendment Act (PAAA) of 1988 amended the Atomic Energy Act of 1954 by providing broad, mandatory, indemnification coverage to all persons, including DOE contractors, subcontractors, and suppliers, whose activities as related to DOE nuclear facilities might result in public liability claims under the PAAA.

In December 1991, the DOE published a proposed Rule[25], 10 CFR PART 830, in the Federal Register, to provide basic requirements for ensuring nuclear safety at DOE facilities. The initial version of the Rule, issued in 1994, included quality assurance requirements drawn from DOE Order 414.1A. It was later revised on January 10, 2001, to add safety basis requirements and integrate with the DOE Safety Management System Policy. This version was issued as a final Rule that was effective on February 9, 2001. The Quality Assurance Rule is now defined in 10 CFR 830, Subpart A, Quality Assurance.

Unlike the contractually enforced DOE Orders, 10 CFR Part 830 provides a basis for enforcement and for civil and criminal penalties under the authority established by the PAAA. Information on the Department's nuclear safety enforcement program is available at http://eh.doe.gov/enforce/.

The DOE Safety Management Rule, 10 CFR Part 830, had finally established fully enforceable quality assurance rules with civil and criminal penalties for its nuclear facilities similar to the NRC's 10 CFR 50 Appendix B for commercial nuclear facilities.

DOE Order 414.1C

The latest revision of the DOE quality assurance Orders 414C[26], superseding DOE Order 414.1B, includes new requirements and guidance for nuclear facility safety software[27]. The Order invokes ASME NQA-1-2000 for implementing these new requirements. DOE has developed a companion guide, G 414.1-4, for implementation of the new requirements, which further describes the requirements, and use of ASME NQA-1-2000. More information on safety software is available at http://eh.doe.gov/sqa.

Implementation Guides

As previously mentioned, DOE and its contractors have had various interpretations on how to implement the independent and management assessment requirements of 10 CFR Part 830.120 and DOE 5700.6C. Therefore, DOE developed and issued a guide[28] under Danielson's direction, on the purpose, types, planning, conduct and reporting of assessments. Later, Danielson managed the development, issuance and updating of an implementation guide for 10 CFR 830.120 and DOE

[24] DOE G 414.1-3, Suspect Counterfeit Items Guide for use with 10 CFR 830 subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance.
[25] U.S. Department of Energy, 10 CFR PART 830, December 9, 1991.

[26] DOE Order 414.1C, Quality Assurance, 6-17-05
[27] DOE G 414.1-4, Safety System Software
[28] DOE G 414.1-1, Implementation Guide for Use with Independent and Management Assessment Requirements of 10 CFR Part 830.120 and DOE 5700.6C, Quality Assurance, August 1996.

Order 414.1[29], plus new guides for S/CIs and safety software noted above.

One might have concluded that the ten nuclear quality assurance criteria of DOE Order 5700.6C tended to be masked and diluted by a more contemporary Total Quality Management (what) format. This argument would explain the need for DOE to develop attachments and guidance discussed above on how to implement the Orders and Rule. It would also explain the need for supplemental requirements and guidance found in the ASME NQA-1-2000 discussed in SECTION IV below.

DOE Action Plan

In July 2005, the DOE published an action plan[30] addressing ten lesson learned from the NASA Columbia Space Shuttle catastrophe of February 2003 and Davis-Besse pressure vessel head corrosion event discovered in March 2002 and their applicability to the DOE complex. The primary focus of the working group preparing the DOE Action Plan was on nuclear operational safety in response to a DNFSB Recommendation 2004-1. None of the DOE Action Plan items related specifically to ways of improving NQA preventive actions.

Some of the lessons identified from these occurrences are summarized and modified here for their potential NQA applicability:

Operating experience: Individuals and organizations need to learn lessons from operating experience to avoid repeating errors and improving performance.

External pressures: Budget and schedule priorities must not override safe and reliable operation decisions.

Focus on planning and prevention: Safety and quality efforts should focus more on planning and preventive actions in addition to investigations and corrective actions after an accident or unexpected occurrence.

Technical inquisitiveness: Managers need to encourage employees to freely communicate safety and quality concerns and differing professional opinions.

Complacency: Management must guard against a self-satisfying attitude brought on by good performance metrics and past safety records.

Normalizing deviations: Routine departures from established standards should not be allowed to create a low-probability event to occur.

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[29] DOE G 414.1-2, Quality Assurance Guide for Use with 10 CFR 830.120 and DOE O 414.1, DRAFT June 1998.

[30] DOE Action Plan, Lessons learned from the Columbia Space Shuttle Accident and Davis-Besse Reactor Pressure Vessel Head Corrosion Event, July 2005.

SECTION II.

AEC>NRC REGULATIONS

This section describes AEC/NRC regulatory initiatives to the extent that they have had a direct impact on the development of nuclear quality assurance regulations, standards and guidance on their implementation. It does not describe the interrelationships of 10 CFR Part 50 Appendix B with other quality assurance-related regulations such as Parts 70, 71 and 72.

Early Nuclear Power Plants

Recognition of the need for and the adoption of effective quality assurance regulations, standards, and guidance on their implementation did not come rapidly nor voluntarily to designers, constructors, operators, and the AEC/NRC regulators of licensed nuclear facilities. In early commercial nuclear power plants, as well as in AEC-owned reactors, technology development programs and test facilities, quality was achieved and verified with a minimum of formal, documented practices and procedures. First-generation commercial nuclear power plants and AEC-owned nuclear facilities were relatively small in size and capacity, remotely located, and relatively simple in their design, construction and operation practices. Close-knit teams of highly competent people were in charge of every aspect of design, construction and operation.

It was not uncommon for early commercial nuclear power plants to be designed and constructed as "turnkey" projects by the reactor suppliers and engineer-constructors. Thus, many of the smaller utility owners had minimal involvement in and technical knowledge of, early nuclear plant designs and construction practices until such time that the constructed nuclear plants were formally turned over to them for operation. Some utilities were focused on producing electricity, and aside from generating costs, did not really care whether the plant was run on coal, oil, gas, hydroelectric or nuclear power. Furthermore, except for applying the quality assurance provisions of the ASME Boiler and Pressure Vessel Code, there was little interest in developing and applying unique quality assurance standards, per se, to other nuclear safety-related components and activities...

In March 1967, Vice-Admiral Rickover offered his advice on designing, constructing and testing to purchasers of central station nuclear power plants under the popular "turnkey" arrangement[31]. For example, he would require the "seller" to define the standards to be used for design, material, fabrication, etc. He would require the "purchaser" to retain an independent organization to check and audit all phases of design and construction. He would require the "seller" to guarantee that the plant would perform reliably: satisfactory performance of equipment for one year and 95% availability

As nuclear facilities grew in size, complexity, and number, as less experienced people became involved, and as their differences from non-nuclear power plants were fully recognized, it became apparent that a more systematic, disciplined, engineering approach to assuring nuclear facility quality was urgently needed.

Sufficient experience in designing and operating first and second generation nuclear plants had not been accumulated until the early 1970s, when the level of nuclear plant construction activities really exploded, to prove conclusively that the nuclear industry and the AEC had no option but to pay the price for more exacting quality standards, regulations and more disciplined work practices for implementing them. Major cultural and systemic changes throughout the industry were of paramount importance if the nation was to succeed in the development and commercialization of safe and reliable nuclear power.

Accordingly, the AEC undertook certain long-term regulatory initiatives to formalize quality assurance programs and standards for the licensing of commercial nuclear power plants. Among these initiatives were the:

1. Developing quality assurance regulations and safety guides.

[31] Address by Adm H.G. Rickover, "Advice to Prospective Purchasers of Central Station Nuclear Power Plants", AEC Authorizing Legislation Hearings before the Congressional Joint Committee on Atomic Energy, Washington, D.C., March 14 & 15, 1967.

2. Implementing the broad definition of quality assurance expressed by Commissioner Ramey that transcended the traditional manufacturing quality control and inspection concepts

3. Providing leadership, financial and technical assistance to an infrastructure dedicated to developing urgently needed national consensus quality assurance standards.

AEC 10 CFR 50 Appendix A[32]

In 1965, the AEC issued a press release designating a series of 27 general design criteria for light-water-cooled nuclear power plants. These criteria were published for public comment in 1967 as Appendix A to 10 CFR50. They were greatly expanded to 55 and then to 64 criteria and made effective as an AEC regulation in 1971. Criterion 1 of Appendix A, "Quality Standards and Records", contains three fundamental quality assurance requirements:

1. Identification, evaluation and use of appropriate quality standards;

2. A quality assurance program to assure that structures, systems, and components performed their safety functions; and

3. Maintenance of appropriate records.

Dresden 2 was the first nuclear power plant to be governed by Appendix A to 10 CFR50.

One might have argued that the three fundamental requirements of Criterion 1 of 10 CFR Part 50 Appendix A together was a sufficient regulation for quality assurance in the design and construction of nuclear power plants; however, on-site AEC regulatory inspections and audits in the 1950s and 1960s at commercial nuclear power plants belied this argument by revealed numerous repetitive generic design and constructions deficiencies, including:

- Inadequate review of detailed designs

- Inadequate quality provisions in purchase specifications

- Inadequate control of suppliers

- Inadequate process controls for shop and field work

- Inadequate control of materials handling and lifting operations

- Inadequate construction inspection

- Inadequate quality records and their control

To cite a few specific examples, AEC inspections at Oyster Creek found continuing quality-related problems in control rod drives, steam separator and cracks in the core shroud and supports. At Big Rock Points, AEC inspectors found defects in fuel assembly welds. At Ginna, AEC inspectors found equipment and personnel hatch frame buckling during concrete placement. The AEC developed internal inspector training programs and inspection procedures. An ongoing discovery was that off-the-shelf commercial products were not always of sufficient quality for nuclear plant service conditions.

Prior to late 1968, however, quality assurance requirements, standards and implementing procedures or the lack thereof was not a major licensing issue of the AEC, the ACRS and the ASLB at CP hearings.

Eventually, it became increasingly apparent to the AEC inspectors and regulatory staff and to the nuclear utility industry that, as the number of applications for nuclear power plant construction permits and operating licenses grew and quality problems were being discovered at plant sites, more definitive quality assurance regulations, standards, and guidance on their application were needed beyond Appendix A to 10 CFR part 50. More importantly, a major paradigm shift was needed to counter a limited construction management attitude that, if the AEC/NRC inspector did not find a quality problem, it didn't exist and must not be reported.

Zion Station Hearings Impact

[32] Contributed by Doug Brown, former ASME NQA MC Chair and currently MC member.

On September 17, 1968, the lack of definitive quality assurance regulations, standards, and guidance caused the Atomic Safety and Licensing Board (ASLB) to suspend public hearings on Commonwealth Edison's (ComEd) Zion Station Units 1 and 2. The ASLB refused to issue a CP by stating:

> ***"In the opinion of the Board, Commonwealth Edison has not presented sufficient evidence pertinent to the provisions that should be made for the assurance of the control of quality needed for the technology and disciplines of the nuclear reactor field, nor has the AEC staff submitted evidence by way of criteria or expert testimony adequate to permit a judgment of its evaluation of the quality control program".***

The ASLB members who presided over the public hearings were:

- S. Jensch
- J. Buck
- S. Forbes
-

Notwithstanding the ACRS asking about but receiving no commitment on "methods of quality control" during the previous Turkey Point 3&4 CP review in 1967, the Zion hearings was a first and major milestone in the history of nuclear power quality assurance program commitment, requirements and eventual regulation in the United States. It had the potential for giving the highest visibility to the development and enforcement of quality assurance program regulations and standards against which the regulatory staff and the applicants could mutually judge the adequacy of the latter's quality assurance programs.

When the ASLB hearings were suspended, ComEd contracted with the Aerojet General Corporation in Sacramento, California, to develop a quality plan and procedures. Concurrently, Wilbur (Bill) Morrison[33] of the AEC Division of Reactor Standards (DRS) and Gene Langston of AEC/RDT were tasked by the DRS Director to began developing a set of quality assurance program criteria to judge the adequacy of ComEd's Zion Station quality assurance program.

[33] W.M. (Bill) Morrison was the first AEC/NRC representative to the ASME N45-3 and ASME NQA Committees

Morrison and Langston extracted applicable provisions from MIL-Q-9858A, NASA NHB 5500.4(1B) and RDT F2-2T quality assurance documents into a series of draft DRS nuclear power plant quality assurance criteria:

- 10/3/68: First draft, 15 criteria A –P.

- 11/12-20/68: Second draft, 20 criteria, 1 – 21, added purpose, definitions, program, control of special processes, mandatory inspection hold points and test control.

On November 26, a joint AEC meeting was held to discuss the scope, timing and criteria that had been developed for a special on-site quality assurance inspection or survey of Common Edison's quality assurance program for Zion reactors.[34] Attending the meeting held in Bethesda, Maryland, were:

- Chuck. Long, DRL
- Bill Morrison, DRS
- Gene Langston, RDT
- Harry Thornburg, CO
- Gerry Hadlock, OGC

The Zion reactors construction site was visited on December 3, 1968 by the inspection team. Commonwealth Edison's engineering and management offices in Chicago, IL, were visited on December 3, 1968. Chicago Bridge and Iron Company, fabricator of containment liner plates, was visited on December 4, 1968. The team met on December 6, 1968, in Bethesda to correlate inspection results and prepare a report for the AEC and ASLB.

[34] Minutes of Commonwealth Edison Company's (CE) Zion Reactors Pre-hearing Inspection Meeting Held on November 26, 1968.

When the ASLB reconvened hearings on December 17, 1968, one ASLB mentioned he had witnessed a concrete form failure at Dresden and questioned whether a quality assurance program could have prevented this failure. ComEd management responded that it would be doubtful.

Morrison and Langston testified as expert witnesses for the AEC on the adequacy of Commonwealth Edison's quality assurance program. Salient observations during the ASLB hearings were:

1. ComEd's quality assurance program had not been very formal or well documented prior to this becoming an issue before the Board.

2. ComEd management contended, without substantial opposition, that the quality assurance program was as formal and as well documented as other cases previously reviewed and approved by the Board.

3. Based on the AEC team's limited on-site survey of the Zion Station construction site and review of ComEd's Quality Assurance Plan, which emphasized documentation and verification, when evaluated against the 15 drafts AEC quality assurance criteria, the AEC staff concluded that the applicant had developed and documented a philosophically acceptable quality assurance plan.[35]. The CP was issued to ComEd for the Zion Station.

4. It was recognized, however, that (1 the plan had not been fully implemented and (2 that some quality assurance elements had not been full investigated, and (3) changes to the plan and implementing processes and procedures would be needed as experience in their implementation was gained.

5. The applicant committed albeit reluctantly to fully implement the Zion Quality Assurance Plan by all contractors working in the site by January 1, 1969, and implementing procedures by February 1, 1969.

6. It should have been more apparent to the AEC Commissioners and the nuclear power industry that quality assurance would become an increasingly important consideration in the AEC licensing reviews in future hearings, especially for plants in the proximity of metropolitan areas.

Quality Assurance Redefined

While NASA and RDT had previously established performance-focused quality assurance program standards and definitions, other early government quality standards, such as MIL-Q-9858A and QC-1 were focused on compliance with contractual quality control and acceptance inspection systems requirements. 10 CFR 50 Appendix B adopted a more encompassing definition of quality assurance, which was a slightly modified version of AEC Commissioner Ramey's:

> ***"All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service."***

This definition infers, for example, that design criteria and standards are adequately defined and correctly translated into design documents; that competent persons execute the design in accordance with the design documents; that tests confirm the design; perform construction and that the plant is operated and maintained within safe limits established by the design.

The 10 CFR 50 Appendix B definition of quality assurance included quality control:

> ***"Those quality assurance actions which provide a means to control and measure the characteristics of an item, process, or facility to established requirements."***

10 CFR 50 Appendix B

Following the Zion Station hearings of the ASLB on December 17, 1969, representatives of the AEC DRS and RDT staff continued to develop the quality assurance program criteria for nuclear power plants. Criteria were added and modified for the control of

[35] "AEC Regulatory Staff Evaluation of Commonwealth Edison's Quality Assurance Program for the Zion Station", December 17, 1968.

special processes, the control of design, inspection and test and other quality-affecting activities. The list of criteria grew to 21 and finally stabilized at 18.

The proposed AEC 10 CFR 50 Appendix B would require applicant for licenses to include in preliminary safety analysis report a description and evaluation of the quality assurance program to be applied to the design, fabrication, construction and testing of structures, systems and components of the facility. The proposed 10 CFR 50 Appendix B also would require that the final safety analysis report contain information concerning measures to be taken to assure safe operation of the facility, including such things as management and administrative controls and plans for operations and maintenance, surveillance, and periodic testing of structures, systems and components.

The proposed criteria would apply to all structures, systems and components of nuclear power plants that prevent or mitigate the consequences of accidents, which can cause undue risk to public health and safety. The requirements would apply to all activities affecting the safety-related function of these structures, systems and components throughout the design, construction and operation phases. Specific activities covered in these phases would include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, refueling, maintaining, repairing, and modifying.

On January 3, 1969, the DRS Director submitted to the ACRS for their review a draft of the quality assurance program criteria for nuclear power plants.

Concurrently, the DRS Director provided the draft quality assurance criteria to RDT for review and comment. RDT formed a steering committee whose members represented the AEC national laboratories and contractors. The membership included:

- Joe Anderson
- Gordon Beer
- Jim Bell
- Stuart Knight
- Gene Langston (Chair)
- Jack Norris
- Herb Ross
- Ralph Seidensticker
- Al Squires

The RDT steering committee met on January 14 and 15, 1969, with W. Morrison and others of the DRS staff. RDT provided numerous comments and recommendations on the draft quality assurance criteria for nuclear power plants:
The RDT steering committee had also recommended adding two new criteria, one for training and another for operation and maintenance control that were not accepted by DRS.

Following the AEC Commissioners' review on March 24, 1969 the AEC published the proposed 18 quality assurance criteria of Appendix B to 10 CFR 50 in the Federal Register on April 17, 1969 for public comment 50[36].

During the 15 month-period for public comment, the newly formed N45-3 Subcommittee reviewed and provided numerous constructive and critical comments on the proposed 10 CFR 50 Appendix B amendment. These comments were sent to the AEC regulatory staff for resolution and to RDT for information[37].

Some of the nuclear industry comments criticized the proposed Appendix B quality assurance criteria by saying they contained prescriptive requirements instead of general criteria for judging the adequacy of an applicant's quality assurance program. Other comments criticized an overemphasis on the mechanics and techniques of meeting the proposed criteria, as opposed to simply defining criteria and leaving implementation details to applicants. Another criticism was that the criteria were rigidly tied to the specific heading, some of which were seemingly redundant, e.g., Sections IV, V and VII for document control. The requirement for exhaustive documentation was perceived as resulting in too much attention to records to the detriment of performance.

Because of the numerous nuclear industry and RDT steering committee comments, the AEC DRS staff

[36] Appendix B to Quality Assurance Criteria for Nuclear Power Plants, Federal Register, vol 34, no 73, April 17, 1969.
[37] Principal changes to Title 10, Chapter 1, Atomic Energy Commission, Part 50, Licensing of Production and Utilization Facilities, Quality Assurance Criteria for Nuclear Power Plants, undated.

made the following changes to the proposed quality assurance criteria of 10 CFR 50 Appendix B:

Section III, Design Control, was extensively revised "to (a) provide provisions to assure that the appropriate quality standards are included in design documents and that deviations from such standards are controlled, (b) require that measures are established for the selection and review for suitability of application of materials, parts, equipment and components; (c) indicate that design control may include methods of verifying or checking the adequacy of design other than the performance of design reviews, such as the use of alternate or simplified calculational methods or the performance of a suitable testing program; and (d) require that design changes be subject to design control measures commensurate with those applied to the original design".

Section IV, Procurement Document Control, was modified "to recognize that all sections of the quality assurance criteria might not be applicable to all contractors or subcontractors".

Section V, Instructions, Procedures, and Drawings, was revised "to make clear that the criteria for determining that important activities have been satisfactorily accomplished need not be duplicated on more that one design document".

Section VII, Control of Purchased Material, equipment, and Services, was expanded "to require that documentary evidence that such items conform to procurement requirements shall be available at the nuclear power plant site prior to installation or use".
Section VIII, Identification and Control of Materials, Parts, and Components, was revised "to eliminate the implication that traceability of items id required in all cases".

Section VIII, Identification and Control of Materials, Parts, and Components, was revised to eliminate the implication that traceability is required in all cases.

Section X, Inspection, was revised "(a) to eliminate the implication that in-process inspection and mandatory hold points are, in all cases, required and (b) to indicate that the inspection program shall be established and executed by or for the organization performing the inspection activity, and that inspection shall be performed by individuals other than those who performed the activity being inspected".

Section XIV, Inspection, Test, and Operating Status, deleted the requirement for marking nonconforming items "to eliminate duplication with the requirements of Section XV". The section was also revised "to indicate that tagging valves and switches is one way to identify the operating status, but not necessarily the only way".

Section XVI, Corrective Action, was revised "to preclude the necessity of corrective action measures for those conditions adverse to quality which are rarely completely eliminated, such as all weld defects prior to final or acceptance inspection. The requirement that the cause be determined and corrected to preclude repetition" was changed "to apply to significant conditions adverse to quality".

Section XVIII, Audits, "to avoid the implication that personnel performing audits should be qualified to specified requirements, the term 'qualified personnel' was changed "to: appropriately trained personnel".

On November 18, 1969, Edson Case, AEC DRS Director, addressed the ASME Winter Meeting on the proposed Appendix B quality assurance criteria for the design of nuclear power plants.[38] He remarked that many of the concepts of quality assurance were being applied in the design process of nuclear power plants without the designers identifying them as being elements of a quality assurance program. For this reason, the application of quality assurance to the design and operation phases may have appeared to many organizations to be more of a new concept in the nuclear power industry than it really was. Nevertheless, he believed there were also important

[38] Remarks by E.G. Case at the ASME Winter Annual Meeting, "Quality Assurance for Design of Nuclear Power Plants", November 18, 1969.

quality assurance elements that were not being applied routinely to the design, as they should have been. It was time to recognize that quality assurance during design was just as important as quality assurance during construction. In addition to design review by an independent organization, there were other design control techniques, including the use of alternate simplified calculation methods and prototype testing to confirm design adequacy. He noted that design organization interfaces and design change control were also important design control measures.

When 10 CFR 50 Appendix B was issued as a regulation in June 1970[39], only 12 nuclear power plants had operating licenses; numerous other plants were in varying stages of their applications for construction permits and operating licenses. Therefore, older plants had no commitment in their licensing applications to implement the proposed quality assurance criteria of 10 CFR 50 Appendix B. After Appendix B was issued, an applicant had to commit in a licensing application to its quality assurance criteria. Eventually, the AEC regulatory staff obtained commitments to the quality assurance criteria of 10 CFR 50 Appendix B for the previously licensed nuclear power plants.

When 10 CFR Section 50.34(a)(7) became mandatory in 1970, it required an applicant for a license to build a nuclear power plant to submit a description of its quality assurance program per the criteria of 10 CFR 50 Appendix B for the design and construction phase in a section of a Preliminary Safety Analysis Report (PSAR) or in a topical report. The regulatory staff performed a desktop review of an applicant's quality assurance program description prior to issuing a construction permit.

In 1973, the AEC Director of Regulation announced a revised procedure that provided for a more substantive review by the licensing staff of the applicant’s quality assurance program description for design and procurement activities and a site inspection by the compliance staff to verify the applicant's implementation of the quality assurance program as described in the construction permit.

[39] Title 10 – Atomic Energy Commission, Part 50 – Licensing of Production and Utilization Facilities, Quality Assurance Criteria for Nuclear Power Plants, Federal Register, vol 35, no. 125, June 27, 1970.

The ASLB prompted this action during the Consumer Power’s Midland station’s public licensing hearings in March 1973 by stating that:

> ***"No QA program is self-executing. Thus, irrespective of how comprehensive it may appear on paper, the program will be essentially without value unless it is timely, continuously, and properly implemented."***

The Board decided that the AEC must do more than a simple desktop review of the applicant’s quality assurance program to determine whether the Appendix B requirements were met and were being implemented.

Regarding scope, the introduction to 10 CFR 50 Appendix B states that it applies explicitly to activities affecting the safety-related functions of those structures, systems, and components that could cause undue risk to the health and safety of the public. It applies to activities including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

The comparability of Appendix B with MIL-Q-9858 and NASA NHB 5300.4(1B) is illustrated in TABLE I.

<u>Fuel Reprocessing Plants</u>

On Marc 8, 1971[40], The AEC Director of Regulation proposed to the Secretary of the AEC for public comment, an amendment to 10 CFR 50, which was requested by the Director DRS, to apply the same quality assurance requirements of 10 CFR 50 Appendix B for nuclear power plants to the design, construction and operation of those structures, systems and components and activities of fuel reprocessing plants that prevent or mitigate the consequences of accidents which could cause undue risk to the health and safety of the public.

[40] Atomic Energy Commission, “Proposed Amendment to 10 CFR Part 50, Quality Assurance Criteria for Fuel Reprocessing Plants” Marc 8, 1971

Appendix B to 10 CFR 50 was changed to "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants".[41]

The AEC Division of Compliance and OGC concurred in this proposed amendment. RDT also concurred in this recommendation with the comment that RDT would expect that the Commission rules would be further amended to include the same quality assurance requirements for plutonium processing and fabrication plants when they are subject to licensing requirements similar to those for reactors and reprocessing plants. This comment was to be taken into account in developing a proposed amendment to 10 CFR Part 70 to provide for pre-construction review of plutonium processing and fabrication plants.

Appendix B Criterion 1 Amendment

On April 19, 1974, the AEC Director of Regulation proposed a rule change to Criterion I, Organization, of 10 CFR 50 Appendix B to be published in the Federal Register. The rule change was published in January 1975.

Rapid growth in the number of nuclear power plants being planned or built had resulted in the entry of many new organizations into this field. In addition, there had been significant changes in the management arrangements under which nuclear power plants were being built, which had resulted in undertaking of project management functions by organizations having limited experience in the nuclear field. To assist applicant and licensees in the development and implementation of their quality assurance programs, the AEC considered it appropriate to present the Commission's requirements with respect to quality assurance in more detail to supplement the requirements of Criterion I. The development of these requirements took into account the experience accumulated in designing, constructing and operating licensed nuclear power plants and Commission-owned reactors.

[41] Appendix B to Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, September 11, 1971.

The change under consideration by the AEC would require an organization assigned responsibility for assuring that a quality assurance program is established and executed and for verifying that an activity has been correctly performed must have sufficient authority and organizational freedom to initiate, recommend, or provide solutions, and to verify implementation of solutions. This provision is similar to subsection 1.B.201 of NASA's quality assurance standard NHB 5300.4(1B).

Ford Amendment Study[42]

In 1984, the NRC reported on a major study that had been made at the request of Congress on the improvement and assurance of quality in the design and construction of nuclear power plants. Referred to as the Ford Amendment study, NUREG 1055 provided valuable insight into and lessons learned from the failures and successes of nuclear power plant design and construction projects.

The study described quality assurance case studies of failures that had been made in nuclear power plant construction projects in the 1970s at Diablo Canyon, Marble Hill, Midland, South Texas and Zimmer sites. Major quality-related problems that contributed to the failures encountered at these sites might have been avoided if the project managers and the NRC had implemented more rigorously effective quality assurance and regulatory inspection programs.

> ***An important lesson to be learned from this study was that there is a level of change actions – technical, regulatory and procedural – beyond which any project management structure can no longer effectively implement its quality assurance program.***

In some construction projects, there was a tacit delegation by senior management of the responsibility for the ***achievement*** of quality to the NRC-required quality assurance organization whose responsibility was to assist in the ***assurance*** of quality.

[42] "Improving Quality and the Assurance of Quality in the Design and Construction", NUREG 1055. 1984

Perhaps the most disturbing finding in the report was the harassment and intimidation of quality assurance personnel at one or more construction sites.

According to this study, the essential quality-related principles of a successfully managed commercial nuclear power plant projects were:

- Top-down project management commitment to quality is a principal project objective;
- Understanding by top management of the magnitude, complexity and difficulties in designing and constructing a nuclear power plant compared to a conventional steam plant, and the importance of applying exacting engineering and quality standards;
- Prior nuclear facility design and construction experience of key project personnel;
- Quality assurance is implemented as an integral part of a comprehensive management control system; and
- Prompt detection, communication and correction of quality problems in design, effective management oversight of the design process, and the ability to control plant configuration and manage change.

Although often criticized as being too prescriptive and not sufficiently performance based, 10 CFR 50 Appendix B has withstood the test of time during over thirty-plus years of application.

Three Mile Island

In the aftermath of the 1979 accident in Unit 2 at the Metropolitan Edison's Three Mile Island nuclear power plant site southeast of Harrisburg, Pennsylvania, President Jimmy Carter appointed the Kemeny Commission to conduct a comprehensive investigation of the accident and make recommendations based on its findings. The Kemeny Commission report, issued in October 1979, traced the cause of the accident to maintenance errors resulting in, a stuck pressure-relief valve, the loss of crew operational awareness and operator errors that resulted in major core damage, and the unavailability of onsite technical support.

SECTION III.

ANSI>ASME N45.2 STANDARDS

This section describes the development of ANSI and ASME N45.2 quality assurance program standards and its "daughter" standards from 1969 to 1977, the AEC Rainbow" series of guidance documents, and the safety/regulatory guides that endorsed the N45.2 standards.

Recognition of Standards Needs

By the late 1960s, it became evident to the AEC and the nuclear industry that regulations alone were not the most desirable or appropriate way to define management and technical practices for designing, constructing and operating nuclear facilities and their components. Using the ANSI national consensus standards process would permit experts from government, industry, national laboratories, and other public institutions to contribute to the definition of these practices.

> ***Bob Minogue of the AEC DRS staff once remarked: "I went to the codes and standards cupboard and it was bare!"***

With financial backing, significant participation and strong endorsement from the AEC plus industry leadership, a plan for a whole body of urgently needed national consensus standards was formulated. This plan identified and assigned responsibility for the development of a variety of consensus standards to the appropriate technical societies and other standards-writing organizations under the American National Standards Institute (ANSI).

In early 1969, a joint ANSI steering committee consisting of representatives of the ASME and other technical societies identified, among other things, the following seven quality assurance-related standards topics for the construction phase of nuclear power plants:

1. Pressure System Cleaning
2. Packaging, Shipping, Receiving, Handling, Storage
3. Housekeeping (total plant)
4. Installation, Inspection and Testing - Electrical and Instrumentation
5. Inspection and Testing - Structural Steel and Structural Concrete
6. Qualification of Personnel
7. Quality Assurance Program Requirements

Six of these standards were to cover specific work practices associated with construction and possibly manufacturing activities. The seventh standard on quality assurance program requirements was significantly expanded to cover the total range of activities affecting the quality of nuclear power plant structures, systems and components, from initial design through construction and operation, exclusive of those structures, systems and components covered by the ASME Boiler and Pressure Vessel Code. It would be applicable to the plant owner and major participating contractors at every level of the plant construction project.

The ANSI N45 Committee on Reactor Plants and Their Maintenance, sponsored by ASME, was assigned five of the seven standards, including the quality assurance program requirements standard.

ANSI N45.2-1971 Standard

During a meeting at Commonwealth Edison in May 1969, the American National Standards Committee N45 established an Ad Hoc Committee (N45-3.70 on Quality Assurance Program Requirements. The purpose of this committee was to prepare a standard for general industry use that would among other things satisfy the intent and amplify the requirements of the AEC quality assurance regulations and provide a basis for the development of detailed quality assurance practices and procedures. The N45-3.70 Ad Hoc Committee was composed of representatives from the AEC, its national laboratories and key segments of the nuclear industry, including utilities, reactor suppliers, plant engineers, and constructors.

The initial activities of Ad Hoc Committee focused on a critical review of the draft 10 CFR 50 Appendix B criteria and the preparation of consensus comments. A number of these comments were considered when the draft AEC rule was revised and approved for publication.

Following this effort and after extensive discussion, the work group concluded that, consistent with its purpose, the quality assurance program standard should be consistent with the format and amplify the content of the 18 criteria of 10 CFR 50 Appendix B. To expedite the development process, an editorial team within the committee was formed and members of the committee were requested to submit their individual suggestions to the editorial team on the content of the standard. The team then met in Santa Barbara, California, for an intensive four-day series of sessions to incorporate input from the committee members into a coherent document. Practically all of the material submitted by the committee contributors was used and the resulting draft was unanimously accepted by the committee with minimal change.

In August 1970, a new 45-3.7 subcommittee on Nuclear Quality Assurance Standards was formed to provide for consolidation of this and other N45 quality assurance standards. In July 1971, this subcommittee delivered to the American National Standards Committee N45 its initial draft of the quality assurance program requirements standard to be issued for public comment. This subcommittee performed final review of the standard produced by N45-3.7. Prior to publication, the ANSI standard number was first changed to N45.3.0 and then to N45.2. ANSI N45.2 also included definitions and supplemental requirements for design, document and records control, and audits. ANSI N45.2-1971 was approved by the American National Standards Committee N45 and the subsequently by the ANSI Board of Standards Review in October 1971. ANSI N45.2-1971[43] was published in February 1972.

AEC and ASME regulations and codes, as well as other American National Standards, were considered in the development of ANSI N45. The structure and content of the standard were as follows:

[43] American National Standard, ANSI N45.2-1971, "Quality Assurance Program Requirements for Nuclear Power Plants", October 20, 1971.

ANSI N45.2-1971 STRUCTURE

INTRODUCTION
- 1.11 Purpose
- 1.12 Scope
- 1.13 Responsibility
- 1.14 Definitions
- 1.15 Referenced Documents

2. QUALITY ASSURANCE PROGRAM
3. ORGANIZATION
4. DESIGN CONTROL
   - 4.11 General
   - 4.12 Interface Control
   - 4.13 Design Verification
   - 4.14 Change Control
5. PROCIREMENT DOCUMENT CONTROL
6. INSTRUCTIONS, PROCEDURES AND DRAWINGS
7. DOCUMENT CONTROL
8. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES
9. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS
10. CONTROL OF SPECIAL PROCESSES
11. INSPECTION
12. TEST CONTROL
13. CONTROL OF MEASURING AND TEST EQUIPMENT
14. HANDLING STORAGE AND SHIPPING
15. INSPECTION, TEST, AND OPERATING STATUS
16. NONCONFORMING ITEMS
17. CORREECTIVE ACTION
18. QUALITY ASSURANCE RECORDS
19. AUDITS

The ANSI N45.2-1971 set fort the requirements and guidance for planning, managing and implementing overall quality assurance programs for nuclear power plants. These general requirements were intended to be applied to all phases of the quality assurance program and to the total power plant while other codes and standards applied to specific structures, systems and components of the plant, or to specific activities related to the plant design, construction or operation.
The principal difference between the ANSI N45.2-1971 standard requirements and 10 CFR50 Appendix B criteria was in their degree of specificity, which fundamentally supports the reason why N45.2 was

developed: the ANSI N45-2-1971 standard contained supplemental requirements and guidance on quality assurance in its subparagraphs. Appendix B contained only basic criteria, which some industry reviewers found to be appropriate for use as a regulatory requirement and licensing commitment. Appendix B applied directly, using a graded approach, to the applicant (plant owner), whereas ANSI N45-2-1971 applied to any individual organization participating in the nuclear power plant quality assurance program, such as the nuclear reactor system designer and supplier, the plant designer; the plant constructor; and equipment suppliers, as well as the plant owner. Hence the N45.2 standard was to be included or referenced in procurement documents for items and services essential not only to the safe and reliable operation of the plant but also to mission success. Some subcontractors and suppliers have used Appendix B for their quality assurance programs in non-regulatory situations.

Concurrent with the development and publication of the ANSI N45-2-1971 standard, other Ad Hoc Committees of N45 were developing a series of standards that set forth more detailed requirements for certain activities to assure quality of nuclear power plants. These requirements were to be coordinated with the requirements of ANSI N45.2-1971 as they were being developed. In September 1971, these ad hoc committees were changed to working groups. In November 1971, these working groups had the following work practice standards in preparation:

<u>Working Groups</u>	<u>Standards in Preparation</u>
N45-3.1	N45.2.1, Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants
N45-3.2	N45.2.2, Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants…
N45-3.3	N45.2.3, Housekeeping During the Construction Phase of Nuclear Power Plants
N45-3.4	N45.2.4, Installation, Inspection and Testing Requirements for Instrumentation and Electrical Equipment During the Construction of Nuclear Generating Stations
N45-3.5	N45.2.5, Construction Phase Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel for Nuclear Power Plants
N45-3.6	N45.2.6, Qualification of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants
N45-3.8	N45.2.8, Quality Assurance Requirements During Installation, Inspection and Testing of Mechanical Equipment and Piping for the Construction Phase of Nuclear Power Plants
N45-3.9	N45.2.9, Requirements for Quality Assurance Records for Nuclear Power Plants
N45-3.10	N45-2-10, Quality Assurance Terms and Definitions

<u>ASQC Matrix</u>

In October 1973, the Interface Committee of the American Society for Quality Control (ASQC) Nuclear Power Technical Committee met in Groton, Connecticut, to draft a nuclear quality assurance requirements matrix for release in early November. This matrix presented a side-by-side comparison of five quality system standards: 10 CFR 50 Appendix B; ANSI N45.2-1971; ASME SECTION III, NA-4000; RDT F2-2T; and MIL-Q-9858A. Members of the ASQC Interface Committee attending the meeting included:

Tom Colandrea
Fred Hannon
Gene Langston

The express purpose of this Committee, which met for the first time in May 1971, was to respond to the needs of the nuclear power industry by providing education and training in quality standards and regulations and interfacing with technical societies.

AEC Safety Guide 28

In 1970, the AEC developed and published a series of Safety Guides to inform applicants of acceptable solutions to specific safety issues. Consistent with AEC policy to use national consensus standards in the regulatory process, in June 1972 the AEC staff endorsed the ASME N45.2-1971 standard in Safety Guide 28 in June 1972 with only a few regulatory positions.

Later in 1972, the AEC established a new series of Regulatory Guides to cover a broader scope of regulatory interests. Regulatory Guides were issued to describe acceptable ways of implementing federal regulations. According to the AEC, Regulatory Guides were not intended as substitutes for regulations and compliance with them was not mandatory; other methods or solutions were acceptable provided that they permitted positive findings relative to the licensing process.

N45.2 Daughter Standards[44] [45] [46]

After sponsoring the development of the basic N45.2 quality assurance program requirements standard and the initial drafts of work practice standards, N45.2.1 – 2.10, by the working groups, the ANSI Committee N45 established a permanent N45-3 Subcommittee. The subcommittee was given broader responsibilities and representation to serve as a focal point for the completion, coordination, and review of other quality assurance standards under the cognizance of the ANSI Committee N45 and for the development of other quality assurance-related standards.

The ANSI N45-3 Subcommittee embodied the members of the previous subcommittee and ad hoc work groups under N45 sponsorship, and enlisted the support of other technical societies, including the Institute of Electrical and Electronic Engineers (IEEE), the American Institute of Chemical Engineers (AIChE)), the American Society of Civil Engineers (ASCE), and the American Society for Quality Control (ASQC). For example, the IEEE Joint Committee of Nuclear Power Standards (JCNPS) prepared the standard IEEE 336 covering the installation, inspection and testing of Class 1E electrical equipment. The IEEE JCNPS reviewed and approved this standard, which was also recognized as the N45.2.4 standard. Furthermore, the ASCE developed a standard covering installation, and inspection of civil/structural items that was approved by the N45 committee and became N45.2.5.

In addition to the quality assurance standards initiated in 1969, the N45-3 subcommittee recognized that supplemental requirements and non-mandatory guidance would be necessary to effectively implement the basic quality assurance program requirements of the N45 standard in certain key quality-affecting areas. Some of the background for these identified areas is discussed in the following paragraphs:

- **Design:** Although Requirement 3 of N45.2 included basic requirements for the assurance of quality in the design phase, the AEC and industry recognized that more specificity was needed to assure quality for the design of nuclear power plants. The N45-2 Subcommittee formed a work group composed primarily of senior design managers to describe realistic design control practices for nuclear power plants. This effort resulted in the N45.2.11 daughter standard.

- **Procurement:** A similar need was identified to effectively implement quality assurance program requirements in the procurement phase. The N45-2 Subcommittee formed another work group consisting of individual with extensive experience in procurement and shop inspection practices. This group developed the N45.2.13 standard.

- **Auditing and Auditor Qualification:** Industries desire to share audits was a

[44] Contributed by S. Bernsen, former ASME N45-2 Subcommittee chairman and ASME NQA Committee member.
[45] S.A. Bernsen and S.K. Hellman, Nuclear Power Plant Quality Assurance Standards, The Status and Application of ANSI N45-2 Standards, July 1973.
[46] M.E. Langston and A.W. Crevasse, Nuclear Standards and Federal Regulations – Where Are We and Where Are We Going? Presented at the Third Annual National Conference on Nuclear Power.

principal driver for the development of additional requirement and guidance on the performance of audits and the qualification of auditors. Once again, the N45-2 Subcommittee selected highly experienced individuals from industry, the national laboratories and the government to develop two documents: N45.2.12 for auditing quality assurance programs for nuclear power plants and N45.2.23 for qualification of auditors.

- **Records:** Substantive concern was expressed about the types of quality assurance records to be generated and retained for nuclear power plants and their retention periods. Additionally, there was considerable uncertainty about the methods for safeguarding records, particularly during the construction phase as well as during plant operation when rapid access to plant configuration records became vital in an emergency situation. Senior individuals familiar with records management and technical needs for records during all phases of the plant design, construction, operation, maintenance, modification and repair were assembled by the Subcommittee for a work group to develop the N45.2.9 standard.

Throughout development of these diverse quality assurance standards, the N45-2 Subcommittee demonstrated the unique ability to manage, complete and achieve consensus on a suite of needed standards on an expedited schedule. This approach received recognition of the value of having a single organization to manage, oversee and integrate the development of related standards.

Based on this recognition, in 1973, ANSI, through the Nuclear Technical Advisory Board (NTAB), made changes in the organizational setup for producing nuclear standards. These changes included the use of Area Managers for nuclear standards development under general requirements suggested by ANSI. The ASME N45-2 Subcommittee took the position that it would the Area Manager for nuclear quality assurance standards and so a smaller advisory group within the subcommittee was formed.

The supplemental quality assurance standards became known as “daughter” standards to the overall N45.2 programmatic standard. ANSI N45.2 daughter standards consisted of two basic types:

1. Those standards that amplified the programmatic aspects of the parent N45.2 quality assurance program standard, and

2. Those standards that focused on quality-related work practices.

The seven ANSI N45.2 programmatic daughter standards and the corresponding Regulatory Guides that endorsed them were:

N45.2.6-1978	Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants (Reg. Guide 1.58)
N45.2.9-1979	Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants (Reg. Guide 1.88)
N45.2.10-1973	Quality Assurance Terms and Definitions (Reg. Guide 1.74)
N45.2.11-1974	Quality Assurance Requirements for the Design of Nuclear Power Plants Reg. Guide 1.64)
N45.2.12-1977	Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants (Reg. Guide 1.144)
N45.2.13-1976	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants (Reg. Guide 1.23)
N45.2.23-1978	Qualification of Quality Assurance Program Audit

Personnel for Nuclear Power Plants (Reg. Guide 1.146)

Each of the standards issued by the N45-2 Subcommittee was subjected to an intensive preparation and review process to ensure that they contained precise statement of acceptable current practices for commercial nuclear power plants – practices that were currently available and considered necessary to achieve the required level of quality, consistent with 10 CFR 50 Appendix B.

AEC Rainbow Series

In the early 1970's, the nuclear industry's implementation of the quality assurance criteria of 10 CFR Part 50 Appendix B was variable and inconsistent. Many of the ANSI N45.2 quality assurance daughter standards were still under development. Guidance was lacking on acceptable quality assurance practices for the relatively few nuclear power plants that were in operation and for the large number of plants nearing completion. More dialogue between nuclear industry and regulatory management was needed to better understand what was required to implement an effective N45.2 quality assurance program in compliance with 10 CFR Part 50 Appendix B.

In June 1973, in conjunction with a new AEC regulatory review process, AEC Commissioner L. Manning Muntzing directed the AEC DRS regulatory staff to issued a series of guidance documents, the first referred to as the “Gray Book” (WASH 1283) to provide guidance on quality assurance requirements during the design and procurement phase of nuclear power plant construction. With the concurrence of the N45 Standards Committee, the “Gray Book” included the pertinent N45.2 quality assurance standards that had been issued or were nearing completion. In July 1973, the AEC Director of Regulation and staff sponsored a series of regional conferences across the U.S. to discuss the contents of the “Gray Book”.

In October 1973, the AEC regulatory staff issued the second in the series, the “Orange Book” (WASH 1284), to provide additional guidance on quality assurance during the operating phase of nuclear power plants. A second series of regional conferences was held in November 1973 to discuss the “Orange Book”.

In May 1974, the “Gray Book” was redesigned as a compilation of federal regulations, Regulatory Guides, American National Standards, and conference comments pertinent to nuclear power plant quality assurance during design and construction.

Also in May 1974, the third in the Rainbow Series of regulatory document, known as the “Green Book” (WASH 1309), was issued and a final series of regional conferences were held to discuss quality assurance during the construction phase of nuclear power plants.

It is significant to note that an underlying theme for the Rainbow Series of documents was the encouragement by the AEC to use applicable national consensus standards, particularly N45.2 and its daughter standards some of which were recognized as being appropriate even in draft form, to meet the criteria of 10 CFR Part 50 Appendix B. The ANSI N45-3 Subcommittee was pleased with the sustained participation of Bill Morrison of the NRC staff and timely support of the AEC management from the Commissioners, and the directors of reactor standards and licensing, DRS and DRL, and their staffs.

ASME N45-2-1977

The N45 Committee was an American National Standards Committee operation under the ANSI Procedures for Standards Development Committees. Its Secretariat was ASME. In 1975, this changed when ASME became an accredited standards development committee and took over the N45.2 standards. ANSI then terminated the N45 Committee and the ANSI N45.2 standards became ASME N45.2 standards.

Responding to user experience and feedback and the perceived need to expand quality assurance program requirements to encompass other regulated nuclear facilities, a revision of the ANSI N45.2 standard was published in 1977. Accordingly, the title and scope of the standard was changed to "ASME N45-2-1977, Quality Assurance Program Requirements for Nuclear Facilities". This change provided for the application of the ASME N45.2 standard to nuclear facilities for power generation, spent nuclear fuel storage, fuel reprocessing, and plutonium processing and fuel fabrication. This change was consistent with the extended applicability of 10 CFR Part 50 Appendix B to Parts 70, which applies to fuel reprocessing facilities.

Revisions 1 (1978) and 2 (1979) to Regulatory Guide 1.28 (formerly Safety Guide 28) endorsed the N45.2-1977 edition with only a few supplemental regulatory positions. Revision 3 of NRC Regulatory Guide 1.28 permitted applicants to follow either the appropriate ANSI/ASME N45.2-series of standards or endorsed ANSI/ASME NQA-1-1983 and ANSI/ASME NQA-1a-1983 addenda with Regulatory Positions on:

- Qualifications of Inspection and Test Personnel
- Quality assurance records retention times
- Internal and external quality assurance program audits

SECTION IV.

ASME AND RELATED NQA STANDARDS

This section describes the evolution of the ASME NQA-1and other "N" committees quality assurance program requirements standards; the consolidation of the ASME N45.2 work practice standards and ASME NQA-1 standards, and their restructuring of the ASME NQA standards from 1979 to 2004.

"N" Committees Standards

Under what had begun as a generally harmonious cover of ANSI "N" Committees for nuclear standards development, jurisdictional and redundancy concerns arose in the 1970's among the various sponsoring technical societies, including ASME (N45), IEEE (N41), ANS (N18), and AIChE (N46).

ANS N18.7(3.2) Standards[47]

Preparation of the first edition of the ANSI/ANS 3.2 standard commenced in 1969. Historically, the administrative controls section of the Facility Operating License Technical Specifications contained provisions for meeting many of the requirements that subsequently became associated with the quality assurance requirements for nuclear power plant operation. During the same period, the ANSI N45-3 Subcommittee was developing N45.2 quality assurance standards.

In 1972, the AEC issued Safety Guide 33, endorsing Draft 8 of ANS 3.2 (which later became ANSI N18.7-1972) and ANSI/ANSI N45.2-1971. Because of this dual NRC endorsement, the ANS 3.2 and N45-2 standards-writing groups undertook a cooperative effort to incorporate the appropriate quality assurance requirements for operation into a single standard. The result was ANSI N18.7-1976 (ANS 3.2), which was endorsed by NRC Regulatory Guide 1.33, Revision 2, in February 1978.

Following the Three Mile Island Unit 2 accident in 1979, ANS revised N18.7-1976 to incorporate administrative "lessons learned" into the standard, which was subsequently published as ANSI/ANS 3.2-1982. This revision also reflected the requirements of ASME NQA-1-1979 discussed below, which had superseded several of the N45.2 daughter standard that had been referenced in N18.7-1976. NRC Regulatory Guide 1.33, Revision 2, dated February 1978, endorsed this revision.

The 1988 and 1994 versions of ANS 3.2 continued strong emphasis on operational aspects and performance-based quality assurance practices.

ANSI N46.2 Standards

Paralleling the development of the ANSI N45.2 standards, the N46 Committee sponsored by AIChE drafted a quality assurance program standard for fuel cycle facilities that was similar to ANSI N45.2 in its format and requirements, In 1978, the ANSI N46-2 Committee issued Revision 1 of its ANSI N46.2-1978 standard for Post-Reactor Nuclear Fuel Cycle Facilities as an American National Standard. By joint agreement between ASME and AIChE to use N45.2, N46.2 was withdrawn.

ASME NQA Committee

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Recognizing the need to minimize redundancy in similar requirements and for clearer definition of responsibilities for quality assurance program standards development and maintenance for nuclear facility applications, early in 1975, the ANSI Nuclear Standards Management Board (NSMB) issued a policy bulletin stating that:

> ***"There should be a single quality assurance standard for nuclear activities"***

Consequently, the NSMB under ANSI assigned overall responsibility for development, coordination among other technical societies, and maintenance of quality assurance program standards for nuclear facility applications, which included the N45.2 standards, to the N45 Subcommittee. Because of this NSMB policy pronouncement, the chairs of the N45 and N46 efforts agreed to merge their committees and develop a single standard covering both scopes. Subsequently, ANSI modified its policy to allow standards-writing organizations to develop and approve standards using their own procedures,

[47] Contributed by Charles Moseley, NQA Committee member and ANS 3-2 Committee liaison

provided these procedures met ANSI consensus requirements. The organizations' standards then could be submitted to ANSI for their approval. Such standards could be designated as products of the organization and carry the statement that they were American National Standards. In response to this policy, the ASME Board of Nuclear Codes and Standards was formed to manage ASME nuclear standards efforts. In October 1975, the N45 Committee transferred quality assurance standards responsibility to a newly constituted ASME Committee on Nuclear Quality Assurance (NQA).

In a special report[48] on "QA Standards – Application and Problems", John Landis, President of Gulf General Atomic Company and chairman of ANSI referred to the new ASME NQA Committee that would carry on and expand the work of the former ANSI N45-3 Subcommittee.

ASME NQA-1-1979

Because different N45-3 working groups had developed numerous interrelated N45.2 daughter standards at different times, these various standards contained some redundant and conflicting quality assurance program requirements, causing users and regulators confusion in their application, endorsement and enforcement. The N45-3 Subcommittee had decided early on that it was more important to issue these urgently needed standards and obtain feedback from industry on their use rather than delay their development and issuance process to attempt harmonization of redundant requirements. It was always the Subcommittee's intent to consolidate them at some point into a single document.

In 1979, ANSI N46.2 Committee merged with the ASME NQA Committee to jointly produced ASME NQA-1-1979, which integrated ASME N45-2-1977 and ANSI N46.2-1978.[49]

The need to consolidate the N45.2 series of standards was also firmly supported by the ASME as a means for amplifying the quality assurance provisions of the ASME Boiler and Pressure Vessel Code to make them more compatible with regulatory requirements.

The task of the new ASME NQA Committee was to consolidate the quality assurance program requirements of the ASME N45.2-1977 standard and the seven N45.2.6 - 2.23 programmatic daughter standards listed above into a single standard. Toward this objective, the new NQA Committee adopted the following approach to consolidation:

- The 18 criteria structure of Appendix B would be preserved as basic requirements.
- These basic requirements would provide an overview of the quality assurance program logic and would be sufficiently general to have wide applicability.
- More specific, detailed requirements would be contained in supplements.
- Requirements would be clearly separated from guidance, the latter being contained in non-mandatory appendices.
- The full expertise of ASME and other standards-writing societies would be employed in developing, coordinating, and maintaining the standard.
- The standard would provide for flexibility in its application as well as growth or reduction of supplementary requirements and guidance.
- Redundancy and conflicts in programmatic requirements would be minimized.

[48] Introductory Remarks by J. W. Landis extracted from the Proceedings of the Executive Conference on Quality Assurance held in San Diego in April 1976.
[49] ASME NQA-1-1979. Quality Assurance Program Requirements for Nuclear Facilities, August 31, 1979.

The standard would not be as limited as 10 CFR 50Appendix B is to safety-related structures, systems components, and associated activities but would be applicable also to those items and activities that were essential to the achievement of project objectives and assurance of reliable operation.

As illustrated in Table 1I in this document below, the newly consolidated and restructured ASME NQA-1-1979 standard was restructured as basic requirements, supplements and appendices, as follows:

- Retained the 18 Basic Requirements structure of 10 CFR Part 50 Appendix B.

- Incorporated detailed requirements and guidance from the seven programmatic daughter standards separately in Supplements and non-mandatory Appendices.

- Reworded Basic Requirements using clear and concise language, such as "The design shall be defined, controlled, and verified..." instead of the obtuse language of Appendix B, i.e., "Measures shall be established to…"

Three members of the ASME NQA Committee, Gordon Beer, Bud Crevasse and the Gene Langston met in Consolidated Edison's New York City office and literally cut and pasted the reworded draft of the ASME- NQA-1-1979 standard. The revised draft standard was further reviewed and edited by the ASME NQA Committee and approved through the consensus balloting process.

ASME NQA-1-1983

The ASME NQA Committee made minor changes in wording of the requirements and guidance in the 1983 edition and two addenda to ASME NQA-1.[50]

In August 1984, the NRC endorsed ASME NQA-1-1983 in Revision 3 to Regulatory Guide 1.28 in August 1985 with only three regulatory positions. These regulatory positions were concerned with the qualification of inspection, test, and nondestructive examination personnel; quality assurance records; and audit frequency. While the NRC has not consistently endorsed successive revisions after the 1983 edition, several licensees have had their quality assurance program approved to a version a more recent version of the standard.

ASME NQA-1-1986

The ASME NQA Committee issued three addenda to the ASME –NQA-1-1986 edition and addenda with relatively minor editorial changes.[51]

ASME NQA-2 STANDARDS

The NQA Committees developed the ASME NQA-2-1983 standard [52] to incorporate the following seven ASME N45.2 daughter standards as parts. ASME NQA.2-1983 standard was amended eight times from 1983 to 1991:

N45.2.1-1980	Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants (NQA-2 Part 2.1)
N45.2.2-1978	Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants (NQA-2 Part 2.2)
N45.2.3-1973	Housekeeping During the Construction Phase of Nuclear Power Plants (NQA-2 Part 2.3)
N45.2.5-1978	Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations During the Construction

[50] ASME NQA-1-1983, issued July 11, 1983
ASME NQA-1a-1983, issued December 31, 1983
ASME NQA-1b-1883, issued March 15, 1985

[51] ASME NQA-1-1986. issued July 11, 1986
ASME NQA-1a-1986, issued February 15, 1997
ASME NQA-1b-1987, issued March 15, 1988
ASME NQA-1c-1988, issued February 28, 1989

[52] ASME NQA-2-1983, Quality Assurance Requirements for Nuclear Facility Applications

	Phase of Nuclear Power Plants (NQA-2 Part 2.5)
N45.2.8-1975	Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for the Construction Phase of Nuclear Power Plants NQA-2 Part 2.8)
N45.2.15-1981	Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants (NQA-2 Part 2.15)
N45.2.20-1979	Supplementary Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants (NQA-2 Part 2.20)

After issuing the ASME NQA-2-1983 edition, the following additional NQA-2 quality assurance work practice standards were incorporated as additional sub-parts of ASME NQA-2-1986 and NQA-2-1989 editions and addenda:

Part 2.4	Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities (IEEE 336)
Part 2.7	Quality Assurance Requirements of Computer Software for Nuclear Facility Applications – Incorporated by reference to IEEE 336
Part 2.16	Requirements for Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities – Incorporated by reference to IEEE 498, subsequently canceled.
Part 2.18	Quality Assurance Requirements for Maintenance of Nuclear Facilities

Referencing parts of NQA-2 standards to another society's standards where the expertise existed seemed like a good idea at the time. However, when these standards were not maintained or were canceled by the other society, (e.g., IEEE 498), ASME N45.2 was left without a valid reference.

ASME NQA-1-1989

In the 1989 edition of ASME NQA-1[53], the ASME NQA Committee incorporated the changes of the 1983 and 1986 editions and their addenda. The scope of ASME NQA-1-1989 was extended to include siting and decommissioning of nuclear facilities. Certain supplementary requirements, such as design control and document control, were clarified or amplified. Three addenda to the 1989 edition were issued in 1990, 1991 and 1992.

ASME NQA-3-1989

Responding to an identified need, in 1984, the ASME NQA Main Committee established a Subcommittee on Nuclear Waste Management. This subcommittee was assigned the task of developing a standard for assuring quality during site characterization of high-level nuclear waste repositories. With the assistance of geotechnical experts from the U.S. Geological Survey and DOE national laboratories and the tacit support of the DOE and NRC, this Subcommittee prepared ANSI/ASME NQA-3-1989[54].

In addition to those activities affecting quality in the ASME NQA-1 standard, ASME NQA-3 contained basic requirements, supplements and non-mandatory appendices on:

[53] ASME NQA-1-1989, "Quality Assurance Program Requirements for Nuclear Facilities, September 15, 1989

[54] ASME NQA-1-1983, "Quality Assurance Program Requirements for the collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories" March 23, 1990.

- Readiness reviews
- Peer reviews
- Data and sample management
- Data collection and analysis
- Coring
- Sampling
- In-situ testing
- Scientific investigation
- Design data process control

In restructuring and consolidating the three ASME NQA standards, NQA-1, NQA-2 and NQA-3, the ASME NQA Committee was undecided about what to do with NQA-3. The reason was that NQA-3 was an application standard for which Part IV of NQA-1 had not yet been established. Thus, according to its Foreword, ASME NQA-3-1989 guidance on the application of NQA-3-type quality assurance programs was expected to be included in future revisions of Part III or Part IV of ASME NQA-1. In the current ASME NQA-1-2004 edition, ASME NQA-3 is embedded in Part III, Subpart 3.3, as a non-mandatory appendix. It is further noted that salient requirements (of NQA-3) will subsequently be integrated into Parts I and/or Part II in a future edition of the ASME NQA-1 standard.

ASME NQA-3-1989 was listed as a source document in Revision 10 of the DOE Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description Document for site characterization work conducted for the DOE Yucca Mountain Project.

ASME NQA-1-1994

In the early 1990's, the ASME NQA Committee leadership perceived that the NQA-1, NQA-2 and NQA-3 standards were not structured in a way that enabled users to understand and apply these three standards. Thus, the NQA Committee decided to consolidate the NQA-1 and NQA-2 standards into a single multi-part document that was intended to allow a more rapid response to varied applications of the NQA standards quality assurance requirements and guidance. The NQA Committee restructured ASME NQA-1-1994[55]. The title was changed to nuclear facility applications" to accommodate the inclusion of NQA-2. The 1994 edition consisted of the following three parts:

- PART I contained an introduction and basic quality assurance program requirements followed by supplementary requirements for nuclear facilities from the former NQA-1 standard.
- PART II included the quality assurance requirements for nuclear facility applications work practices requirements for facility applications as subparts from the former NQA-2 standard. A new subpart 2.21 was added in the 1995 addenda to address quality assurance guidelines for decommissioning nuclear facilities.
- PART III consisted of non-mandatory guidance as subparts in appendices from the former NQA-1 and NQA-2 standards.

ANSI/ASME NQA-3 was not integrated into the restructured NQA-1 standard at this time.

An addendum to the 1994 edition, ASME NQA-1a-1995, was issued on December 7, 1995. It contained a definition of surveillance and a number of editorial changes.

ASME NQA-1-1997

Quality assurance program requirements and guidance included in the NQA-1 standard were derived from and focused primarily on compliance-based practices and after-the-fact verification. Both industry and NRC leadership expressed an interest in revisiting some of the fundamental quality assurance program requirements, including those of Appendix B to 10 CFR Part 50, on performance-based practices. Consequently, a major review and revision effort was initiated by the NQA Committee to

[55] ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications"

improve and update the requirements and guidance in a performance-based NQA-1 standard. Criteria were developed and the standard was revised to complement proven quality assurance program principles and practices that had consistently provided a high level of quality during the past three decades. Performance-based criteria were retained or introduced to ensure safe and reliable nuclear facility operation. Factors related to the current technology and maturity of the nuclear industry were used in evaluating whether the benefits were commensurate with implementation costs and whether the level of detail was appropriate for the desired results.

The specific criteria used for the review and revision of the standard were:[56]

- Is it performance based?
- Does it contribute to safe and reliable nuclear facility operation?
- Are benefits commensurate with implementation costs?
- Is it consistent with current technology and maturity of the nuclear industry?
- Is the level of detail adequate to achieve the desired results?
- Is the level of detail more than the minimum required to produce the desired results?
- For the intended activity, is this the minimum requirement that applies to all applications?
- Is the requirement stated once and not duplicated?

With the expansion of the NQA-1 scope from nuclear power plants to nuclear facilities, minimum requirements that were commonly applicable to nuclear facilities were presented. The NQA Committee also did some housecleaning to further remove redundant phraseology. The most common example of redundancy was to remove "written" or "documented" for quality assurance program-related activities that are generally required or implied to be documented by Requirement 5, “Instructions, Procedures and Drawings” and records maintained in accordance with Requirement 17, “Quality Assurance Records”. However, the NQA Committee was firm in its intention not to delete any basic quality principles or practices that have contributed to the achievement and maintenance of safe and reliable operation in U.S. nuclear facilities. In those cases where there were prescriptive details for compliance with a requirement, this type of information was deliberately moved to guidance as an appendix in Part III.

Seeking to further improve the usability of the NQA - 1 standard, the NQA Committee once again restructured the consolidated ASME NQA-1 standard in the 1997 edition[57], as follows:

- PART I included the Introduction and combined the basic and supplementary requirements for quality assurance programs from the former NQA-1 standard.
- PART II contained the quality assurance requirements for nuclear facility applications as work practices from the former NQA-2 standard.
- PART III consisted of the non-mandatory guidance as appendices and subparts from NQA-1 and NQA-2 and NQA-3.
- PART IV was reserved for non-mandatory guidance as appendices on positions and application matrices, such as Subpart 4.1, Application Appendix - Guidance on Quality Assurance Requirements for Computer Software.

As noted above, changes to the NQA-1-1997 edition and Part I of the 1999 addenda[58] deleted or modified requirements of earlier editions and addenda to further minimize redundancy and eliminate unduly

[56] Contributed by Sid Bernsen, op. cit.

[57] ASME NQA-1-1997, :Quality Assurance Program Requirements for Nuclear Facility Applications”, December 31, 1997

[58] ASME NQA-1a-1999, May 25, 1999

restrictive requirements. Some requirements were changed to useful guidance and included in Part III.

An addendum to the 1997 edition, ASME NQA-1a-1999, was issued on May 25, 1999. It contained a definition of surveillance and a number of editorial changes. A significant change to NQA-1 was made by the complete revision of Subpart 2.7 in Part II, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, to make it compatible with the software quality assurance guidance in Part IV. Requirements 3 and 11 of NQA-1 were also modified to incorporate basic requirements for software development and testing.

ASME NQA-1-2000

This edition[59] continued the NQA Committee practice of providing additional guidance with only minimum change to requirements. Definitions of document and quality assurance record were revised. Requirements 3, Design Control, were minimally revised in the Addenda.

Several non-mandatory appendices were added to PART IV: Subpart 4.1, Guide on Quality Assurance Requirements for Software; and Subpart 4.2, Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development.

The NRC issued a limited endorsement of ASME NQA-1-2000 in Exelon's licensing application for its nuclear facilities.

ASME NQA-1-2004

ASME NQA-1-2004[60] revised the ASME NQA-1-2000 edition by retaining the four-part format that began with the restructuring of the ASME NQA-1-1994 edition. This standard includes the revisions, corrections and editorial changes introduced in the NQA-1a-2002 addenda.

ASME NQA Survey

An ASME NQA survey was conducted in 2004 of the quality assurance program basis for U.S. nuclear power reactors. The survey indicated an encouraging shift of numerous nuclear utilities toward the adoption of the ASME NQA-1 1994 and later standards.

ASME NQA Standards Benefits[61]

The potential benefits of using the ASME NQA standards are:

- Standards are developed by a broad and balanced representation of experts and stockholders with many years of experience in a wide variety of licensed and unlicensed nuclear facilities.
- Standards development is an open process that encourages free expression of views.
- Technical issues are discussed and resolved in a non-confrontational and non-threatening environment.
- Open process provides for public review.
- Standards clearly separate basic and supplementary requirements from non-mandatory guidance.
- Standards are performance based.
- Standards requirements can be applied selectively using a graded approach.
- Standards approval is achieved through a consensus process with no single dominating interest.
- Standards are reviewed and updated in addenda and revised periodically to keep abreast of current industry and regulatory practices.
- Process provides for an opportunity for interpretation and revision of requirements and guidance.

[59] ASME NQA-1-2000, ", May 21, 2001Quality Assurance Program Requirements for Nuclear Facility Application"

[60] ASME NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications, December 22, 2004

[61] Contribute by Sid Bernsen.

- Standards can achieve greater public acceptance and credibility that similar industry practices or regulatory requirements.

SECTION V.

This section describes the early history of the ASME Boiler and Pressure Vessel (B&PV) Code Section III.

ASME B&PV CODE SECTION III [62]

Although not yet required by federal regulations, ASME, as a joint industry-regulatory effort, was capturing those elements critical to pressure-retaining components used in nuclear power plants. In 1963, ASME introduced Section III of the B&PV Code. It contained no quality assurance requirement until the 1967 Amendment. Then Section III contained 15 quality assurance criteria based largely on MIL-Q 9858A, as follows:

ASME B&PV Code Section III Appendix IX Quality Assurance Criteria
• Organization • Quality Assurance Control Program • Description of Procedures • Drawings and Changes • Receiving Examination • Control, Identification and Marking • Manufacturing Fabrication Procedures • Examination • Testing • Calibration • Handling, Storage and Delivery • Component and Material Repair • Quality Control Records • Quality Audits

ASME Section III Appendix IX required ASME to review and approve quality assurance programs. It also required a firm to hire a third-party inspection agency, usually an insurance company.

In 1989, ASME Section III dropped Appendix IX and adopted ASME NQA-1-1989 with Addenda through 1992 as its quality its quality assurance basis.

[62] Contributed by Doug Brown.

ASME Section III added and modified basic and supplemental requirements of NQA-1 with some modification of definitions in NCA 4120 and requirements in NCA 4134 for Division 1 Code activities and in WA 4120 and WA 4134 for Division 3 Code activities.

SECTION VI.

NQA MANAGEMENT ISSUES[63]

Since 1985, when Revision 3 to Regulatory Guide 1.28 endorsed ASME NQA-1-1983, the NRC staff has been reluctant to develop regulatory positions based on the evolution of nuclear quality assurance program requirement, and to endorse current versions of ASME NQA-1. This position was considered by the NRC staff to be reasonable because of the resistance of plant owners and operators to change from previously approved regulatory commitments due to cost and licensing uncertainties. An ASME NQA survey indicates that progress is being made by the nuclear utilities in adopting more current editions of ASME NQA-1. The ASME NQA Committee continues to work toward the broader NRC endorsement of current NQA-1 editions in keeping with a longstanding regulatory policy to endorse national consensus standards. Other ASME NQA Committee management issues are:

- To improve the timeliness of ASME NQA Committee responses to enquires and changing needs and new technologies.

- To take more positive action on NQA Committee initiatives to include performance-based requirements and guidance to complement traditional programmatic compliance elements.

[63] Contributed by T.E. Dunn, Vice Chairman, ASME NQA Committee and Executive Committee member.

SECTION VII.

ASME NQA VISION[64]

Looking to the future of NQA requirements and the ASME NQA standard, one must never forget the need to protect the health and safety of the public. The viability of the nuclear industry is directly linked to its safety record of success. This relationship was validated by the events that occurred at the Three Mile Island nuclear facility in March 1979. However, since then, the record for nuclear utility operational performance has improved dramatically, and facility safety has not been compromised. The industry must continue to focus on those activities and programs that are necessary to maintain safety and realize that this effort must never be sacrificed to achieve performance of financial objectives.

The nuclear industry must again be capable of building new nuclear power generation in the United States. There are many complex issues related to new nuclear power generation, including the application of new quality assurance regulations and the associated consensus standards, including ASME NQA-1, and the experience and technical capability of vendors to supply quality products to complex plants.

New nuclear power generation must embrace the latest technologies and regulations in an efficient and cost effective manner. New technologies must utilize proven quality control concepts based on past performance but tailored to the demands of the new technologies. Regulations for new nuclear power generation must also move out of the past and into today's changing environment without compromising the commitment to safety.

In today's environment of limited resources, standardization is one method of achieving a cost-effective product. This can also apply to the regulation of new nuclear power generation. There needs to be one set of quality assurance requirements related to nuclear power generation because the health and safety of a citizen in New York is just as important to a citizen in Georgia, California or Illinois. Support of the ASME NQA-1 standard with regulatory endorsement is the best method of achieving this standardization. The NQA Committee has been continuously evaluating the NQA-1 standard to address new technologies and regulatory position changes and is ready to be a part of the effort to make new nuclear power generation a viable solution to our nation's energy programs.

Since its inception, the NQA Committee has continued to focus on providing a timely and value-added product to the industry. The Committee vision is for ASME NQA-1 to be recognized as the world-class nuclear quality assurance standard of choice adopted by organization to achieve safe performance and reliable cost-effective operation in all activities while maintaining an acceptable compliance position relative to their respective regulatory requirements. To achieve this, the vision of the NQA Committee will be to continue to pursue the following:

- Develop timely changes to address new and improved technologies, changes in regulations and industry experience.

- Promote the utilization of the latest edition of ASME NQA-1 for all nuclear facilities, including both licensed and unlicensed facilities.

- Seek support, interaction and cooperation of the NRC and other regulatory bodies in the utilization of the latest edition of the ASME NQA-1 standard through a consensus process that minimizes differences between the standard and the accepted industry and regulatory positions.

[64] Contributed by John Adkins, Chairman, ASME NQA Committee

TABLE I: DOD MIL-Q-9858A, NASA NHB 5300.4(1B) AND NRC 10 CFR 50 APPENDIX B COMPARISON		
DOD MIL-Q-9858A **QUALITY PROGRAM REQUIREMENTS**	**NASA NHB 5300.4(1B)** **Quality Program Provisions for Aeronautical and Space System Contractors**	**AEC/NRC 10 CFR Part 50 Appendix B** **Quality Assurance Criteria for Nuclear Power Plants**
1.1 Applicability	Chapter 1: INTRODUCTION	Introduction
1.2 Summary	1B100 General	II. Quality Assurance Program
3.1 Organization	1B201 ORGANIZATION	I. Organization
3.2 Initial Quality Planning	Chapter 2: QUALITY PROGRAM MANAGEMENT AND PLANNING 1B 200 GENERAL 1B202 TRAINING	II. Quality Assurance Program
3.3 Work Instructions	1B 203 QUALITY INFORMATION 1B 300 TECHNICAL DOCUMENT	V. Instructions, Procedures, and Drawings VI. Document Control
	CHAPTER 3: DESIGN AND DEVELOPMENT CONTROLS 1B 300 TECHNICAL DOCUMENTS 1B 302 CHANGE CONTROL	III. Design Control
3.4 Records	1B405 DATA RETRIEBAL OF RECORDS	XVII. Quality Assurance Records
3.5 Corrective Action	1b802/1B907 REMEDIAL AND PREVENTIVE ACTION	XVI. Corrective Action
4.1 Drawings		V. Instructions, Procedures, and Drawings
4.2 Measuring and Test Equipment	CHAPTER 9: METROLOGY CONTROLS	XII. Control of Measuring and Test Equipment
5.0 Control of Purchases 5.1 Responsibility 5.2 Purchasing Data	CHAPTER 5: PROCUREMENT CONTROL 1B501 SELECTION OF CONTRACTOR PROCUREMENT SOURCES 1B502 PROCUREMENT DOCUMENTS	IV. Procurement Document Control VII. Control of Purchased Equipment and Services
6.1 Materials and Material Control	CHAPTER 4: IDENTIFICATION AND DATA RETRIVAL	VIII. Identification and Control of Materials, Parts, and Components
6.2 Production Processing and Fabrication	CHAPTER 6: FABRICATION CONTROLS	IX. Control of Special Processes
6.3 Completed Item Inspection and Test	1b704 END-ITEM INSPECTION AND TEST SPECIFICATIONS AND PROCEDURES	X. Inspection XI. Test Control
6.4 Handling, Storage and Delivery	CHAPTER 11: HANDLING, STORAGE, ETC	XIII. Handling, Storage and Shipping
6.5 Nonconforming Material	CHAPER 8: NONCONFORMING ARTICLE AND MATERIAL CONTROL	XV. Nonconforming Materials, Parts, or Components
6.6 Statistical Quality Control and Analysis	CHAPTER 12: SAMPLING PLANS, STATISTICAL PLANNING AND ANALYSIS	
6.7 Indication of Inspection Status	CHAPTER 10: STAMP CONTROLS	XIV. Inspection, Test, and Operating Status
7.2 Government Property	CHAPTER 13: GOVERNMENT PROPERTY CONTROL	
	1B205 QUALITY ROGRAM AUDITS	XVIII. Audits

Table 1I ANSI/ASME NQA-1-1979 STRUCTURE

	BASIC REQUIREMENTS	SUPPLEMENTS	APPENDICES
1	Organization	1S-1 Organization	1A-1 Organization
2	Quality Assurance Program	2S-1 Qualification of Inspection and Test Personnel 2S-2 Qualification of Nondestructive Examination Personnel 2S-3 Qualification of Audit Personnel 2S-4 Personnel Indoctrination and Training	2A-1 Qualifications of Inspection and Test Personnel 2A-2 Quality Assurance Programs 2A-3 Education and Experience of Lead Auditors
3	Design Control	3S-1 Design Control	3A-1 Design Control
4	Procurement Document Control	4S-1 Procurement Document Control	4A-1 Procurement Document Control
5	Instructions, Procedures, and Drawings		
6	Document Control	6S-1 Document Control	
7	Control of Purchased Items and Services	7S-1 Control of Purchased Items and Services	7A-1 Control of Purchased Items and Services
8	Identification and Control of Items	8S-1 Identification and Control of Items	
9	Control of Processes	9S-1 Control of Processes	
10	Inspection	10S-1 Inspection	
11	Test Control	11S-1 Test Control	
12	Control of Measuring and Test Equipment	12S-1 Control of Measuring and Test Equipment	
13	Handling, Storage, and Shipping	13S-1 Handling, Storage, and Shipping	
14	Inspection, Test, and Operating Status		
15	Control of Nonconforming Items	15S-1 Control of Nonconforming Items	
16	Corrective Action		16A-1 Corrective action
17	Quality Assurance Records	17S-1 Quality Assurance Records	17A-1 QA records
18	Audits	18S-1 Audits	18A-1 Audits

ATTACHMENT: ASME NQA-1-2004 BASIC REQUIREMENTS AND PRACTICES[65]

BASIC REQUIREMENT 1: ORGANIZATION
Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority and lines of communication for activities affecting quality shall be documented.

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- Management is responsible for establishing and ensuring the adequacy and effectiveness of the organization's quality assurance program.
- The quality assurance staff assists management in establishing the quality assurance program and ensuring its effectiveness but top or senior managers are ultimately responsible for quality.
- The quality assurance staff is provided an open line to management to resolve quality problems.
- Organizational independence means that the quality assurance staff is allowed to assess and report on the quality assurance program compliance to top and senior managers but does not preclude the quality assurance staff from contributing to mission success and continual quality improvement.

BASIC REQUIREMENT 2: QUALITY ASSURANCE PROGRAM
(a) A documented quality assurance program shall be planned, implemented and maintained in accordance with this Part (Part 1), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide for control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.

(b) The program shall provide for the indoctrination, training and qualification as necessary of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.

(c) Management shall regularly assess the adequacy and effectives of the quality assurance program.

- The quality assurance program is the composite of plans and actions that define a management system, not just a document.
- The quality assurance program considers public and worker safety, environmental protection, and mission success.
- The management organization having overall responsibility for the quality assurance program decides what parts it will implement and what parts it will assign to others to implement.
- For expected results, those who are to achieve these results must know what to do, have the resources and be competent to do it.
- Realistic quality objectives are established and measured to provide managers sufficient confidence that the quality assurance program policies and requirements will be achieved as planned.

[65] Contributed by Joe. Anderson

BASIC REQUIREMENT 3: DESIGN CONROL
The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

- The design is the solution to a defined need, not just the documents.
- Design is accomplished through a controlled process.
- The objective of design control is to provide confidence that what is required or desired will result by implementing the design.
- Design interface control encompasses both the design process and design organizations.
- In most cases, there is significant time and many actions that are required between design completion and full implementation of the design for construction and operation.
- Peer review is one way to verify design adequacy
- Design changes are controlled to preserve confidence in the design.

BASIC REQUIREMENT 4: PROCUREMENT DOCUMENT CONTROL
Applicable design bases and other requirements necessary to ensure adequate quality shall be included or referenced in documents for procurement of item and services. To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

- Procurement of items and services involves a legally enforceable contract between the buyer and supplier.
- To ensure adequate quality, the contract documents is clearly stated and understood by the Supplier complete in their content, and legally enforceable.
- Procurement documents define both the technical requirements, including the quality characteristics of the item or service being procured, as well as the quality assurance activities that have been delegated to the Supplier to implement under the contract.
- Procurement documents and their changes are controlled.

BASIC REQUIREMENT 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS
Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, and drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. The activity shall be described to a level commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for and level of detail in written procedures or instructions shall be determined based on complexity of the task, work environment, and worker proficiency and capability (education, training, experience).

- Most failures to achieve quality in items and services can be traced to poor communications.
- NQA-1 requirements underscore the importance of conformance to instructions, procedures, and drawings to prevent or overcome failures due to inadequate communications.
- Inadequate communications can results in failure to be aware of and follow properly updated and maintained procedures and instructions.
- Instructional material is in a form and contains substance that is readily understood by users.

BASIC REQUIREMENT 6: DOCUMENT CONTROL
The preparation, issue, and change of documents that specify quality requirements of prescribed activities affecting quality such as instructions, proce3dures, and drawings shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

- The right documents must be in the right places, in the right hands, and recognizable as being the correct authorized version for the work being performed.
- Obsolete versions of documents are controlled to prevented misuse on items and activities important to quality.

BASIC REQUIREMENT 7: CONTROL OF PURCHASED ITEMS AND SERVICES
The procurement of items and services shall be controlled to assure conformance with specified requirements. Control shall provide for the following, as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items and services upon delivery or completion.

- The buyer make sure by monitoring that the supplier knows what is important and why before there is an opportunity for supplier produces an unacceptable item.
- The buyer plans and performs actions that direct and control supplier performance to ensure satisfaction of contracted requirements.
- Evidence of suppler performance may only be captured during the event necessitating pre-arrangements to gather such evidence.
- Cooperation between the buyer and supplier is mutually beneficial for contract oversight.

BASIC REQUIREMENT 8: IDENTIFICATION AND CONTROL OF ITEMS
Controls shall be established to ensure that only correct and accepted items are used or installed. Identification shall be maintained on the item or in documents traceable to the items, or in a manner that assures that identification is established and maintained.

- Any item that is important to quality must be identifiable and traceable in the event of a problem.
- Item identification is necessary to ensure the correct item is installed and used.
- Item identification is essential to effective configuration management and maintenance of limited shelf life materials.

BASIC REQUIREMENT 9: CONTROL OF SPECIAL PROCESSES
Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

- Quality assurance programs, as defined by NQA-1, generally apply to the control classical special processes, such as welding and nondestructive examination.
- There may be other special processes that meet the intent of NQA-1 definition and that also need special skills, training, procedures, and environmental controls to assure quality.

BASIC REQUIREMENT 10: INSPECTION

Inspection required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

- To maximize value, inspections are planned, performed in accordance with procedures or instructions, results analyzed, and documented.
- Inspections may be performed for various reasons beyond simply measuring conformance to requirements such as operational or in-service preventive maintenance.
- Inspections for acceptance are performed by those independent to those who performed the work.

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BASIC REQUIREMENT 11: TEST CONTROL
Tests required to collect data such as for siting or design input, to verify conformance of an item, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

- Testing is performed for a multitude of purposes besides verifying conformance to specified requirements. Examples include development testing where acceptance criteria have not yet been established.
- Regardless of purpose, testing is planned, performed in accordance with procedures, results analyzed, and documented.

BASIC REQUIREMENT 12: CONTROL OF MEASURING AND TEST EQUIPMENT
Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified intervals, adjusted, and maintained to required accuracy limits.

- It is important to understand the risks associated with using unreliable or uncelebrated M&TE
- M&TE precision and accuracy must be understood when selecting M&TE.

BASIC REQUIREMENT 13: HANDLING, STORAGE, AND SHIPPING
Handling, storage, cleaning, packaging, shipping and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be controlled in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent procedures specified for conducting the activity.

- Improper protection of high-cost or sensitive items can results in avoidable costs.
- The credibility of expensive items that have been qualified and certified and damaged subsequently is compromised.
- Improper handling, lifting and rigging of items has resulted in numerous incidents of personal injury.

BASIC REQUIREMENT 14: INSPECTION, TEST, AND OPERATING STATUS
The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not installed, used or operated.

- Methods for identifying and maintaining inspection and test status are identified, maintained and readily available to workers as work progresses.
- Methods for identifying operating status, including temporary hookups changes, are essential to avoid serious injury, accidents or accidents.

BASIC REQUIREMENT 15: CONTROL OF NONCONFORMING ITEMS
Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

- Controlling nonconforming items is essential to assure the acceptability of the completed item, its readiness to perform an intended function, and maintaining contractual and regulatory compliance.
- Improper dispositioning of nonconforming items, such as suspect/counterfeit items, may have hazardous consequences.
- Nonconformances are evaluated for lessons learned.

BASIC REQUIREMENT 16: CORRECTIVE ACTION
Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to prevent recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.

- Corrective action goes beyond the correction of a deviation from a specification. Depending upon the significance, corrective action includes:
    - Identification of the causes of the nonconforming conditions adverse to quality.
    - Determination of similarity to previous nonconformances
    - Deciding on preventive action to preclude reoccurrence
    - Communicating occurrence to other organizations that may benefit from the corrective and preventive actions taken.

BASIC REQUIREMENT 17: QUALITY ASSURANCE RECORDS
Quality assurance records shall furnish documentary evidence that items or services meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their disposition specified. Requirements and responsibilities for these activities shall be documented. The term records, used throughout this section, is to be interpreted as quality assurance records.

- To have confidence in achieved quality and enable future work and investigations, the results must be recorded and readily available.
- Some nuclear power plants were not completed and were prematurely decommissioned, due in part to the lack of recorded evidence of work performed.
- Adequate quality assurance records reflect well planned and managed work
- Adequate quality assurance records may play a pivotal role in decommissioning plants and dispositioning their components.

BASIC REQUIREMENT 18: AUDITS
Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

- A quality audit is a disciplined process for assessing performance of quality assurance activities in support of judgments of responsible managers regarding adequacy and effectiveness.
- Such audits are not to be used to determine product acceptance but may influence this determination.
- An audit is a sampling process and, therefore, to be effective, is conducted by trained, experienced and qualified auditors who are skilled in drawing conclusions concerning significance.
- From these conclusions, responsible management determines how to correct an observed inadequacy and improve upon the program.
- An audit may also identify best or exemplary practices and recommended actions for improvement.
- Audits may be supplemented by real-time surveillance of work in progress or other evaluations.
- Audits provide input to management reviews and assessments