ASME NQA.TR-2020

Evolution of Quality Assurance Principles and Requirements in the U.S. Nuclear Industry

AN ASME TECHNICAL REPORT

The American Society of Mechanical Engineers

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Two Park Avenue, New York, NY 10016-5990

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FOREWORD

This Technical Report provides a historical summary of the principles, practices, and requirements of quality assurance standards across the nuclear industry from 1954 to the present. It details the origins of nuclear quality assurance techniques such as quality control and inspection requirements during World War II, and the subsequent nuclear vessel codes and standards that emerged in the early 1960s. The purposes of and benefits derived from these early engineering efforts are provided with their historical context. This Technical Report provides a thorough timeline of the evolution of quality assurance across the nuclear industry (primarily in the United States) and a discussion of today's practices to ensure high integrity in the design, operation, and decommission of U.S. nuclear facilities.

Merritt E. (Gene) Langston — a long-time member of the ASME NQA Standards Committee and its de facto historian — was the principal author of the original 2005 draft of this Technical Report. Mr. Langston coauthored quality assurance requirements of the U.S. Nuclear Regulatory Commission (NRC) regulation 10 C.F.R 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants; the U.S. Atomic Energy Commission Reactor Development and Technology (AEC RDT) document F2-2T, Quality Assurance Program Requirements; and U.S. Department of Energy (DOE) Order 5700.6, Quality Assurance. He was a charter member of the former ASME N45-3 Subcommittee and a former member of the ASME Committee on NQA. Subsequent contributors to this Technical Report include staff from the NRC and the DOE, and members of ASME Codes and Standards Committees.

ASME NQA Standards Committee is committed to maintaining this Technical Report to benefit the entire nuclear industry. It will help provide young professionals and "newcomer nations" to nuclear power with the historical foundations for the principles, practices, and requirements used to ensure the safe and reliable use of nuclear energy.

ASME NQA COMMITTEE
Nuclear Quality Assurance

(The following is the roster of the Standards Committee at the time of approval of this Technical Report.)

STANDARDS COMMITTEE

CORRESPONDENCE WITH THE NQA COMMITTEE

General. ASME Codes, Standards, and Technical Reports are developed and maintained with the intent to represent the consensus of concerned interests. As such, users of this Technical Report may interact with the Committee by proposing revisions and attending Committee meetings. Correspondence should be addressed to:

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The American Society of Mechanical Engineers
Two Park Avenue
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Proposing Revisions. Revisions are made periodically to the Technical Report to incorporate changes that appear necessary or desirable, as demonstrated by the experience gained from the application of the Technical Report. Approved revisions will be published periodically.

The Committee welcomes proposals for revisions to this Technical Report. Such proposals should be as specific as possible, citing the paragraph number(s), the proposed wording, and a detailed description of the reasons for the proposal, including any pertinent documentation.

Attending Committee Meetings. The NQA Standards Committee regularly holds meetings and/or telephone conferences that are open to the public. Persons wishing to attend any meeting and/or telephone conference should contact the Secretary of the NQA Standards Committee.

EXECUTIVE SUMMARY

This Technical Report provides an accounting of the continuing evolution of quality assurance principles, practices, and requirements for nuclear facility applications in the United States since 1954. Sections 1 through 5 describe how nuclear quality assurance (NQA) and its documentation have evolved along four separate yet interrelated paths, as follows:

(a) standards and directives from the U.S. Atomic Energy Commission (AEC), then the Energy Research and Development Administration (ERDA), then the Department of Energy (DOE)

(b) regulations and regulatory guides first from AEC and subsequently from the U.S. Nuclear Regulatory Commission (NRC)

(c) ANSI N45.2 and subsequently ASME NQA-1 and related standards

(d) ASME Boiler and Pressure Vessel Code (BPVC), Section III

These first five Sections track 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 the American Society of Mechanical Engineers' (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 6 outlines ASME NQA management issues the ASME NQA Committee vision.

At the onset of nuclear power generation in the United States, AEC regulators and nuclear utility owners were primarily concerned with ensuring safe plant operation without due regard to formal management controls that were essential for ensuring 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 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 NQA activities have also included 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 ASME NQA Committee envisions an additional section documenting

– a broader adoption by the nuclear industry of ASME NQA-1 standards
– a growing application of the standards to DOE reactor and non-reactor nuclear facilities
– a more timely endorsement by the NRC of successive versions of the standards beyond 1994

NOTE: At its April 2004 meeting, the ASME NQA Committee approved a task proposal notice 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 today. This Technical Report is not a part of ASME NQA-1.

PREFACE[1]

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, collectively, the foundation standard for extension to other pressure-retaining nuclear components rules. With the initial edition of the nuclear vessel code, Section III of the ASME BPVC, ASME provided a tutorial guide that was extremely helpful for 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, the recognized father of naval nuclear propulsion, spoke of a "cultural lag" in nuclear power plant management and manufacturing.[2] He said industry practices were not geared to the higher standards imposed by the new power reactor technology. He laid out the following three principles for improving quality management:

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

(b) Specifications must be clearly understood, respected, and enforced by manufacturers as well as customers.

(c) 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, PA, nuclear plant. At that time, 8 reactors with a combined capacity of 4,870 megawatts electrical (MWe) were on order. In the first 8 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 total MWe to 110,000 total MWe by 1980. Plant capacity had increased in size from several hundred megawatts electrical to 1,100 MWe, including multiple units at some sites, such as Commonwealth Edison's Dresden, IL, generating station. Also, plants were being located in proximity to largely populated metropolitan areas.

This rapid growth in nuclear power plant orders and construction in the 1960s 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 following questions:

– 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 Reactor Development and Technology (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 (ANS) in 1966, Commissioner Ramey defined quality assurance as comprising "all actions necessary to provide adequate confidence that a product or facility will operate satisfactorily in service."[3]

This definition was consistent with the U.S. Department of Defense (DOD) military specification MIL-STD-109, which defined quality assurance as "a planned and systematic pattern of all activities necessary to provide adequate confidence that the item or product conforms to established technical requirements."[4]

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[1] This Preface was contributed by Joe Anderson, former Chair of the ASME N45-2 Subcommittee and former member of the ASME NQA Committee and Applications Subcommittee.

[2] Address by Vice Admiral Hyman. G. Rickover, "The Never-Ending Challenge," 44th Annual National Metals Congress, New York, NY, October 29, 1962.

[3] Address by AEC Commissioner James T. Ramey, "Quality Assurance as a Matter of Public Policy in the Safety of Atomic Power Plants," 1966 Winter Meeting of the American Nuclear Society, Pittsburgh, PA, November 2, 1966.

[4] Reference to MIL-STD-109 definition of "quality assurance" was contributed by Robert Hartstern, former member, ASME NQA Committee.

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.[5] 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 Title 10 of the Code of Federal Regulation, Part 50 (10 C.F.R. 50). In response to Appendix B, the ASME-sponsored American National Standards N45 Committee formed a quality assurance subcommittee to develop standards for implementing quality assurance standards. This subcommittee subsequently became the ASME Nuclear Quality Assurance (NQA) Committee. Since their inception, these ASME standards committees have carefully preserved the early definition and the enlightened 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 their programs to ANSI N45.2 and later to ASME NQA-1. 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 the late 1960s and 1970s, many of the skilled workers in the U.S. nuclear industry who managed, designed, and constructed these plants moved to other careers, retired, or were nearing retirement. Today, the nuclear industry is approaching the same situation it initially faced in the early 1960s: a lack of knowledgeable and skilled management, technical, and quality assurance professionals. A tremendous amount of accumulated experience and best practices have been developed, documented, and codified over the past 70 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 for the next generation of managers, technical specialists, and nuclear quality assurance professionals. The ASME NQA Committee intends that this Technical Report will be 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.

ACRONYMS

The following acronyms are used in this Technical Report:

Acronym	Definition	Acronym	Definition
ACRS	Advisory Committee for Reactor Safeguards	FFTF	Fast Flux Test Facility
AEC	U.S. Atomic Energy Commission	GOCO	Government-owned, contractor-operated
AIChE	American Institute of Chemical Engineers	IEEE	Institute of Electrical and Electronics Engineers
AL	Albuquerque Operations Office	MWe	Megawatts electrical
ANS	American Nuclear Society	NASA	National Aeronautics and Space Administration
ANSI	American National Standards Institute	NFPQT	Nuclear Facility Personnel Qualification and Training Committee
ASLB	Atomic Safety and Licensing Board	NNSA	National Nuclear Security Administration
ASME	The American Society of Mechanical Engineers	NQA	Nuclear quality assurance
BPVC	Boiler and Pressure Vessel Code	NRC	U.S. Nuclear Regulatory Commission
C.F.R.	Code of Federal Regulations	NSMB	Nuclear Standards Management Board
CP	Construction permit	OMB	Office of Management and Budget
CRD	Contractor requirements document	PAAA	Price Anderson Amendments Act
DNFSB	Defense Nuclear Facilities Safety Board	QC	Quality control
DOD	U.S. Department of Defense	RDT	Reactor development and technology
DOE	U.S. Department of Energy	SFO	Santa Fe Operations Office
DP	Defense Program	SNAP	Space Nuclear Auxiliary Power
DRS	AEC Division of Reactor Standards		
ERDA	Energy Research and Development Administration		

[5] 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.

TIME LINE

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 today:

1954 The Atomic Energy Act of 1954 amended the Atomic Energy Act of 1946, defined the AEC function, and established the AEC in Germantown, MD, and Washington, DC, encompassing both regulatory and developmental functions.

AEC Santa Fe Operations Office issued QC-1, Weapon Quality Policy, prescribing nuclear weapons production quality control and inspection practices.

1956 Dresden 1 and Indian Point 1 [Note (1)] received the first AEC construction permits (CPs) under 10 C.F.R. 50, with no specified quality assurance program criteria or requirements.

1963 ASME issued ASME BPVC, Section III, with no specified quality assurance requirements.

1965–1967 AEC developed a proposed Appendix A to 10 C.F.R. 50 covering nuclear power plant design criteria. Criterion 1, Quality Standards and Records, required the following:

(a) quality standards
(b) a quality assurance program
(c) quality records for structures, systems, and components important to safety

1966 The Fermi 1 [Note (1)] incident resulted from unauthorized design changes causing partial reactor core meltdown. Also, AEC reported ten reactors that had been in operation for approximately $2\frac{1}{2}$ years were then closed.

1967 During its review of the CPs for Turkey Point 3 and 4 [Note (1)], the ACRS asked about but did not pursue methods of quality control.

ASME published ASME BPVC, Section III, Appendix IX, containing 15 quality assurance criteria and requiring ASME review and approval.

During its review of the CPs for Browns Ferry 1 and 2 [Note (1)], ACRS found a lesser commitment to quality assurance. ACRS was concerned because these were the first reactors to exceed 1,000 MWe.

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

1968 ASLB suspended public hearings on a Commonwealth Edison application to design and construct a nuclear power plant because the license applicant did not have a quality assurance program for the plant and the AEC did not have criteria for evaluating the adequacy of the applicant's quality assurance program.

1969 The AEC RDT Division developed and issued a comprehensive quality assurance program standard, AEC RDT F2-2T, for its GOCO reactors and test facilities.

AEC regulatory department proposed for public comment 18 quality assurance criteria as Appendix B to 10 C.F.R. 50 for licensing nuclear power plants.

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 public comment period and a trial use at Surry [Note (1)], the AEC issued 18 quality assurance criteria for nuclear power plants as 10 C.F.R. 50, Appendix B, thereby expanding upon Criterion 1 of 10 C.F.R. 50, Appendix A.

1971 AEC issued 10 C.F.R. 50, Appendix A.

AEC expanded 10 C.F.R. 50, Appendix B, to apply the 18 quality assurance criteria to fuel-reprocessing plants as well as to nuclear power plants.

ANSI N45.2-1971 was issued. Supplementary ANSI N45.2 standards (referred to as daughter standards) were issued in subsequent years.

1972 ANS published ANS 3.2-1972 for administrative controls during nuclear power plant operation.

1974 The Energy Reorganization Act of 1974 abolished the AEC and established separate agencies: the NRC and the ERDA.

Due to some organizational issues at LaSalle and Midland [Note (1)], the AEC and then the NRC proposed an amendment to Criterion 1, Organization, of 10 C.F.R. 50, Appendix B, with regard to permissible organizational relationships; the Criterion 1 amendment was approved and issued early in 1975.

1975 ASME established the ASME Committee on Nuclear Quality Assurance to continue developing, coordinating, consolidating, and restructuring nuclear quality assurance standards.

Browns Ferry [Note (1)] fire occurred.

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

ERDA was abolished with the creation of the U.S. Department of Energy.

1978 ANSI N46-2 Committee issued Revision 1 of ANSI N46.2-1978, Quality Assurance Program Requirements for Post-Reactor Nuclear Fuel Cycle Facilities, which was subsequently withdrawn.

1979 Three Mile Island Unit 2 [Note (1)] 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.

ASME NQA Committee issued ANSI/ASME NQA-1–1979 on quality assurance requirements for nuclear facilities.

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

1983 ASME NQA Committee issued ANSI/ASME NQA-1–1983.

ASME BPVC, Section III, adopted ANSI/ASME NQA-1–1979 edition.

ASME NQA Committee incorporated seven ANSI/ASME N45.2 daughter standards as Parts of ANSI/ASME NQA-2–1983.

1985 NRC endorsed ASME NQA-1–1983 in Revision 3 of NRC 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.

1991 NRC endorsed ASME NQA-1 and ASME NQA-2 in NUREG-0800.

DOE published a proposed Nuclear Safety Management Rule under 10 C.F.R. 830 and § 830.120 on quality assurance. DOE also issued DOE O 5700.6C, 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 C.F.R. 830 and § 830.120. The Rule provided for civil and criminal penalties similar to the NRC rules for commercial nuclear facilities.

ASME NQA Committee issued ASME NQA-1–1994, Quality Assurance Requirements for Nuclear Facility Applications.

1997 ASME NQA Committee issued ASME NQA-1–1997 with continued restructuring and removal of redundant text.

1998 DOE O 414.1 was issued in November 1998. This Order was superseded by DOE O 414.1A in May 1999 and by DOE O 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, which contained numerous revisions to the 2000 edition.

DOE/NNSA issued Revision 10 of QC-1 on DOE weapon quality policy.

2005 DOE O 414.1C superseded DOE O 414.1B. DOE O 414.1C contained requirements for safety software.

DOE published Action Plan based on lessons learned from the Columbia Space Shuttle accident and Davis–Besse [Note (1)] reactor pressure-vessel head corrosion event.

2008 ASME NQA Committee issued ASME NQA-1–2008 with the new work-practice requirements on commercial grade dedication in Subpart 2.14.

DOE Office of Environmental Management issued EM-QA-001, Quality Assurance Program, which required consideration of all Parts of ASME NQA-1.

2009 ASME NQA Committee issued the ASME NQA-1a–2009 addenda linking Subpart 2.14 on commercial grade dedication and Subpart 2.7 on acquired software and safety functions.

2010 NRC endorsed ASME NQA-1–2008 and the ASME NQA-1a–2009 addenda with the issuance of Revision 4 of NRC Regulatory 1.28.

2011 ASME NQA Committee issued the ASME NQA-1b–2011 addenda, which included revision of para. 100 titles in Part I from “Basic” to “General” and the beginning of the Part II revisions.

DOE issued DOE O 414.1D, which superseded DOE O 414.1C. The revision required the use of ASME NQA-1–2008 with ASME NQA-1a–2009 for activities passing Critical Decision Phase 1 (CD-1).

2012 ASME NQA Committee issued ASME NQA-1–2012. The edition contained numerous revisions to Part II Subparts; the addition of Subpart 2.22 on management assessments within the DOE; and revision and restructuring to the Subparts of Parts III and IV [notably the addition of guidance on commercial grade dedication of software (3.2-2.14), and the redesignation of the research and development guide as Subpart 4.2.1 (previously Subpart 4.2)].

2013 DOE/NNSA issued NAP-24 on DOE weapon quality policy that superseded QC-1 Revision 10. NAP-24 described the minimum quality requirements for the NNSA and NNSA contractors and subcontractors responsible for activities specific to phases 1 through 7 of the weapon life cycle. Requirements were aimed at ensuring customer requirements are met during all seven phases of weapon and weapon-related product realization — from concept definition to disposal.

DOE/NNSA issued NAP 24A, a revision of NAP-24, NNSA Weapon Quality Policy. NAP-24A added content that replaced the NNSA Office of Defense Programs (NA-10) Weapon Quality Assurance Procedures Manual and incorporated new NNSA Nuclear Enterprise Assurance policies.

2015 ASME NQA Committee issued ASME NQA-1–2015. In this edition, the committee continued its efforts to enhance the understanding and usability of the Standard (e.g., Parts II, III, and IV). Of particular note were the consolidation of the majority of software requirements in Subpart 2.7, and guidance on the relationship between the software requirements and guidance. An initial set of process flow diagrams for the software requirements of ASME NQA-1a–2009 was included to assist in the implementation of ASME NQA-1–2008 with the 2009 addenda. A guide on the peer-review process was also developed and included in this edition.

2017 ASME NQA Committee issued ASME NQA-1–2017. The edition was revised to address requirements and guidance for use of electronic quality assurance records and supplier accreditation for calibration and testing services. Guidance for control of nonconforming items was revised, and minor changes were made to the graded approach for applying ASME NQA-1 to research and development projects. Additionally, the full set of process flow diagrams for the software requirements of ASME NQA-1a–2009 was completed to better assist in the implementation of ASME NQA-1–2008 with the 2009 addenda.

NOTE: (1) This time line uses the following abbreviations for U.S. nuclear sites:

Browns Ferry 1 and 2	=	Browns Ferry Nuclear Plant, Units 1 and 2, Athens, AL
Davis–Besse	=	Davis–Besse Nuclear Power Station, Oak Harbor, OH
Dresden 1	=	Dresden Generating Station, Unit 1, Dresden, IL
Fermi 1	=	Enrico Fermi Atomic Power Plant, Unit 1, Newport, MI
Indian Point 1	=	Indian Point Energy Center, Unit 1, Buchanan, NY
LaSalle	=	LaSalle County Generating Station, Marseilles, IL
Midland	=	Midland Nuclear Power Plant, Midland, MI
Surry	=	Surry Nuclear Power Station, Surry, VA
Three Mile Island Unit 2	=	Three Mile Island Nuclear Generating Station, Unit 2, Middletown, PA
Turkey Point 3 and 4	=	Turkey Point Nuclear Generating Station, Units 3 and 4, Homestead, FL

Section 1
AEC and DOE Quality Assurance Requirements and Rules

1.1 SCOPE

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; to the series of DOE quality assurance directives.

1.2 AEC WEAPON QUALITY POLICY, QC-1 AND NAP-24

AEC quality management policy for nuclear weapons complex activities was first documented in the AEC's Santa Fe Operations Office (SFO) Weapon Quality Policy, QC-1. Issued in April 1954, QC-1 predated MIL-Q-9858A,[1] the widely used DOD specification for military quality assurance programs that was issued in 1959.

The initial edition of QC-1 included the following quality control and inspection principals and requirements:

(a) specification and drawing control
(b) quality control procedures
(c) control of inspection gauging and test equipment
(d) production tooling accuracy
(e) in-process inspection and records
(f) control of special processes
(g) SFO/DOE source inspection
(h) 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 ensure, 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 DOD on the behalf of SFO and to arsenals that performed work for the SFO under agreements with DOD.

In 1982, the DOE Assistant Secretary for Military Applications defined,[2] and in 1989 redefined[3] in greater detail, the quality assurance policy for the DOE nuclear weapons complex. This policy required the execution and maintenance of procedures that

– provided control, through plans and actions, over activities affecting quality to an extent consistent with defined programmatic or organizational objectives
– had objective, measurable means to ensure their effectiveness, which were required to be used by management for regular assessments
– emphasized continuous improvement in all activities, including both support and operational organizations
– applied appropriate elements of recognized standards

QC-1 was revised numerous times from its initial issue in 1954 through 2004. In 2013, QC-1, Revision 10, was replaced by National Nuclear Security Administration (NNSA) Policy Letter NAP-24. QC-1 and NAP-24A addressed changes and additional DOE weapon quality policy and quality assurance requirements. Thus, for example, QC-1, Revision 6, issued in 1992, added quality system requirements for training of manufacturing, inspection, and test personnel, and for quality improvement, error prevention versus detection, and nonconformance costs.

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 the DOE nuclear weapons program from complying with DOE quality assurance orders on the basis of equivalency. Then, in 1992, in a memorandum to DOE field office managers,[4] the Assistant Secretary for Defense Programs declared that DP would comply with DOE O 5700.6C (see para. 1.5.2), with certain exemptions for classified weapons production work. The Assistant Secretary decided that it would be to DP's

[1] DOD Military Specification MIL-Q-9858 was issued in April 1959 and superseded by MIL-Q-9858A in December 1963. MIL-Q-9858A was canceled in 1996.

[2] DOE Assistant Secretary for Military Applications, Quality Assurance Policy, November 20, 1982.

[3] DOE Assistant Secretary for Military Applications, Quality Assurance Policy, July 7, 1989.

[4] DOE Defense Programs Memorandum, Implementation of Department of Energy Order 5700.6C, "Quality Assurance," was issued February 27, 1992. It was canceled in 1998 and replaced by the DOE O 414.1 series.

advantage to be able to demonstrate to oversight organizations, e.g., Congress, the NRC, the Environmental Protection Agency, 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. QC-1, Revision 9, issued in late 1998, incorporated into QC-1 the newer quality assurance requirements of QC-2 for nuclear weapons research, design, development, procurement, production, dismantlement, maintenance, stockpile evaluation, and disassembly and disposal.

From QC-1's inception in 1954 to the current NAP-24A, policy, principles, and requirements have placed maximum responsibility and accountability on

– nuclear weapons program prime contractors to maintain effective quality control systems
– the AEC/DOE not only to conduct surveillance and acceptance inspections that focus on functional quality evidence presented by the prime contractors, but also to verify this quality evidence

In February 2004, the DOE/NNSA issued QC-1, Revision 10, superseding Revision 9. QC-1, Revision 10, contained the following significant changes for organizations that were required to comply with DOE weapon quality policy:

– change in ownership of QC-1 from AL to DOE/NNSA Headquarters DP
– new requirement for a management program (quality assurance program or weapon quality assurance program) to be submitted to DOE/NNSA for approval
– major emphasis on a risk-based quality management system for decision making
– greater emphasis on quality metrics

QC-1, Revision 10, was restructured along the lines of ASME NQA-1–2000 to ensure that QC-1 could be implemented using ASME NQA-1. 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 was the DOE/NNSA method for implementing DOE O 414.1A and the DOE Nuclear Safety Management Rule, 10 C.F.R 830, Subpart A. All federal and contractor work relating to nuclear weapons was now covered by the DOE/NNSA quality assurance Order, Rule, and contract direction.

While QC-1, Revision 10, adopted a number of requirements from ASME NQA-1, it included some differences. For example, QC-1 established a two-party government-owned, contractor-operated (GOCO) contractual relationship. Also, QC-1 included the following additional quality assurance requirements:

– metrics
– quality cost management
– control of processes
– process control methods
– government-furnished material
– NNSA-accepted material
– senior management responsibilities

In 2013, NNSA replaced QC-1 with NNSA NAP-24. NAP-24 restructured QC-1 into the standard DOE directive format. It referenced the NNSA supplemental and DOE directives for control of measuring and test equipment and records rather than explicitly including these requirements. Additionally, DOE O 414.1D, Attachment 4, replaced the software quality requirements for safety- and weapons-related software previously in QC-1.

NAP-24 was revised in 2015 to include Attachment 3, which defined common processes and activities for the federal and NNSA contractor (both design agencies and production agencies) weapon quality organizations, employing a layered oversight approach involving Headquarters Weapon Quality Division, field/production offices, and NNSA contractors and subcontractors.

1.3 AEC NAVAL REACTORS, AEC QRC-82C

Quality control requirements for AEC naval nuclear propulsion programs were prescribed in AEC QRC-82C. This document supplemented MIL-Q-9858A by imposing quality control requirements for material inspection and testing during manufacturing of naval reactor components.

1.4 AEC TO 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 RDT management and engineers were disturbed to note that important civilian reactor and technology development objectives 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.

Early AEC, DOE, and contractor project management misconceptions about quality assurance included the following:

(a) Some project managers believed it was possible to ensure 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.

(b) Some project managers believed that 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 that quality and its achievement are primary management responsibilities; 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 AEC–NASA 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 NASA NHB 5300.4(1B) on some of its prime contractors, e.g., Aerojet General in Azusa, CA, and General Electric in Evendale, OH. In MIL-I-45208A, NASA delegated to DOD Air Force, Navy, and other contract administration agencies certain DOD inspection system requirements for nonnuclear, 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 or quality control requirements on the SNAP reactor-system-development contractors. The Associate Director at NASA's Lewis Research Center brought this situation to the attention of the joint AEC–NASA organization.

In mid-1968, senior managers at the AEC Division of Reactor Development and Technology (RDT) 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.[5] 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 NASA NHB 5300.4(1B). The proposed standard would provide requirements 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 Hyman G. 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 maintenance and operation 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.

RDT F2-2T was written in a phased format that could be selectively applied to a facility or project, depending on the scope of the quality assurance program activities. The phases 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.

RDT F2-2T covered all of the basic quality assurance criteria of 10 C.F.R. 50, 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 F2-2T 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 F2-2T was amended ten times from 1969 to 1983 to improve the effectiveness of quality assurance program implementation based on user experience and on unusual occurrences reported during design, construction, and operation of numerous AEC/DOE reactors and test facilities. These amendments included

– purchaser approval of repairs and waivers

– planning and documentation of independent design reviews

– surveillance of facility operations, maintenance, modifications, and repairs

– preparation of engineering drawing lists

– purchaser approval of inspection and test plans and establishment of mandatory hold points

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

– control of handling, lifting, and rigging activities
– selective application of quality assurance requirements and preparation of a quality assurance program index of procedures
– calibration and control of measuring and test equipment
– indoctrination, training, and qualification of personnel
– identification, reporting, and management of engineering holds

In a large construction project, e.g., the DOE's Fast Flux Test Facility (FFTF), special quality assurance requirements and controls were incorporated through these amendments to RDT F2-2T. The amended requirements helped users 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 standard on testing and lifting controls, particularly for lifts 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 Shaw called their attention to the promulgation of RDT F2-2T. This standard reinforced the many policy statements and related actions of Congress, AEC, ACRS, and standards-writing groups over several years on the need to significantly strengthen quality assurance in the conducting of reactor and technology development programs, whether in the national laboratories or in the commercial sector.

In a 1978 memorandum to DOE field office managers,[6] 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 programs were to employ ANSI/ASME N45.2. Where ANSI/ASME N45.2 was determined to be insufficient for technology development activities, it was to be supplemented by appropriate quality assurance requirements.

[6] Assistant Secretary for Energy Technology, Director of Nuclear Energy, Quality Assurance Policy for Nuclear Energy Program, September 1, 1978.

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 RDT F2-2T when it endorsed ANSI/ASME NQA-1–1983. The shift to the ASME 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 RDT F2-2T 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 ANSI/ASME NQA-1–1983, the AEC Division of RDT relinquished its technical and quality management ability to make rapid, timely, and substantive changes to quality assurance program requirements based on urgent needs backed 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.

1.5 DOE ORDERS AND GUIDES

1.5.1 DOE O 5700.6

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

(a) inadequate or nonexistent quality standards
(b) inadequate design control and design reviews
(c) inadequate supplier controls
(d) 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 required only periodic progress reports on activities and spending. The AEC requested but did not direct quality assurance compliance.

In response to the IG advisory, in 1979 the U.S. Secretary of Energy appointed a study group headed by Phil Coyle of DP, and which included the author, to develop recommendations on a department-wide quality assurance policy and requirements. In January 1981, with the concurrence of the Secretary of Energy, DOE O 5700.6 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 DOE O 5700.6 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 Under Secretary of Energy developed a DOE Action Plan. A revised DOE O 5700.6A was issued in an attempt to strengthen the department's dysfunctional quality assurance policy. In September 1986, DOE O 5700.6B addressed only changes in DOE headquarters' responsibility for quality assurance oversight.

1.5.2 DOE O 5700.6C

In August 1991, a completely restructured DOE quality assurance Order, DOE O 5700.6C, was published as a part of a comprehensive DOE directives system. This system includes DOE policies, manuals, Orders, Notices, and Regulatory Rules and Guides for quality assurance plus a variety of many other documents, which may be accessed through the DOE Directives website at www.directives.doe.gov. Information specific to the department's quality assurance policy is available at https://energy.gov/ehss/quality-assurance-policy-and-directives.

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

Category	Criteria
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 O 5700.6C reflected the concept that all work is a process that can be managed, performed, assessed, and improved, i.e., by adopting a management-system approach to quality.

The ten basic criteria of DOE O 5700.6C provided general quality assurance requirements for all work to be performed by DOE and its contractors. The ten criteria were stated as expected (performance-based) outcomes, rather than 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; Criterion 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 O 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 O 5700.6C referenced ASME NQA-1, ASME NQA-2, ASME NQA-3, and a number of DOE and other standards.

Work associated with DOE nuclear weapons production, Naval Nuclear Propulsion programs, NRC licensing, and research and development publications was exempted from DOE O 5700.6C. This Order did not exempt work associated with design construction, operation, and maintenance of facilities and equipment used to produce nuclear weapons.

DOE O 5700.6C required the use of appropriate standards, such as ASME NQA-1 (see subsection 2.4 and section 4), for the development and implementation of quality assurance programs. The Order stressed the three quality management principles and based its performance-oriented quality assurance criteria on 12 underlying principles and actions.

(a) 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.

(3) Overall performance is measured and evaluated using a rigorous assessment process.

(b) Underlying Principles and Actions

(1) Define policies and objectives, and ensure they are understood and accepted.

(2) Specify roles and responsibilities, and ensure they are understood and accepted.

(3) Specify and communicate expectations, and 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, and control changes to them.

(10) Assess work results to ensure they meet requirements and exceed 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 O 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 O 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 O 5700.6C. Where an organization was not in compliance, an implementation plan was required to describe the actions and schedules for achieving compliance.

1.5.3 DOE O 414.1 and DOE O 414.1A[7]

In November 1998, DOE issued a new draft quality assurance directive, DOE O 414.1, for review and comment. The new Order superseded DOE O 5700.6C. It redefined the scope in conjunction with the new DOE Nuclear Safety Management Rule 10 C.F.R. 830 and § 830.120 and § 830.122. The Order applied to both DOE and contractor organizations.

DOE O 414.1 and DOE O 414.1A 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 DOE to gather broad input from national and international standards bodies, standards users, and users of the DOE Order and Guides; DOE charted these committees, which were composed of representatives of DOE, national laboratories, and contractors with expertise in quality assurance, assessments, and management. The QMSIG has since been disbanded.

Attachment 1 of DOE O 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 sections from the Order that apply only to federal organizations (e.g., DOE headquarters and field office responsibilities).

Attachment 2 of DOE O 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 O 414.1A was published in DOE G 414.1-2. This superseded the original guidance in Attachment 1 to DOE O 5700.6C.

1.5.4 DOE O 414.1B

DOE O 414.1B superseded DOE O 414.1A. Its purpose was to ensure that DOE NNSA products and services meet or exceed customer expectations. This objective was to be achieved based on the following principles:

(a) Quality is assured and maintained by a single, integrated, effective quality assurance program, i.e., a management system.

(b) Management support for planning, organization, resources, direction, and control are essential to quality assurance.

(c) Performance and quality improvement require thorough, rigorous assessment and corrective action.

(d) Workers are responsible for achieving and maintaining quality.

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

DOE O 414.1B requirements applied to NNSA and contractor organizations, except for 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 1 and 2 contained essentially the same ten basic quality assurance criteria taken from the superseded DOE O 5700.6C and DOE O 414.1A for DOE and contractor organizations, respectively; Attachment 3 described 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, for controlling S/CI.

1.5.5 DOE Rule 10 C.F.R. 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.

[7] Paragraphs 1.5.3 through 1.5.10 were contributed by Gustave (Bud) Danielson, a member of the ASME NQA Committee at the time of original development of this Technical Report; also, former Vice Chair of the ASME NQA Committee and former Chair of the ASME NQA Executive Committee, International Activities Subcommittee, and Applications Subcommittee.

In December 1991, the DOE published a proposed Rule, 10 C.F.R. 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 O 5700.6C. It was 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 C.F.R 830, Subpart A, Quality Assurance.

Unlike the contractually enforced DOE Orders, 10 C.F.R. 830 provided a basis for enforcement and for civil and criminal penalties under the authority established by the PAAA. Information on the DOE's nuclear safety enforcement program is available at https://energy.gov/ea/services/enforcement.

The DOE Safety Management Rule, 10 C.F.R. 830, had now established fully enforceable quality assurance rules with civil and criminal penalties for its nuclear facilities.

1.5.6 DOE O 414.1C

The DOE O 414C superseded DOE O 414.1B and included new requirements and guidance for nuclear facility safety software The Order invoked ASME NQA-1–2000 for implementing these new requirements. DOE developed a companion guide, DOE G 414.1-4, for implementation of the new requirements and use of ASME NQA-1–2000. More information on safety software is available at https://energy.gov/em/services/nuclear-safety-software-quality-assurance.

1.5.7 DOE O 414.1D

The latest revision of the DOE quality assurance Orders is DOE O 414.1D, which superseded DOE O 414.1C. The Order requires use of national and international consensus standards to address regulatory and contractual requirements. The contractors must identify use of consensus standard(s) in their quality assurance program plan. Due to the nature of work in DOE, more than one consensus standard may be required to address DOE requirements. DOE O 414.1D requires ASME NQA-1–2008 and ASME NQA-1a–2009 (or later edition) for nuclear facility applications.

1.5.8 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 C.F.R § 830.120 and DOE O 5700.6C. Therefore, DOE developed and issued a guide, DOE G 414.1-1, on the purpose, types, planning, conduct, and reporting of assessments. Subsequently DOE developed, issued, and updated its implementation guide for 10 C.F.R § 830.120 and DOE O 414.1-2, plus new guides for S/CIs and safety software.

1.5.8.1 DOE G 414.1-1C. DOE G 414.1-1C provides guidance on performing management and independent assessments in accordance with the DOE quality assurance requirements identified in 10 C.F.R. 830, Subpart A, and in DOE O 414.1D.

1.5.8.2 DOE G 414.1-2B. DOE G 414.1-2B as updated in Administrative Change 2 dated May 8, 2013, provides information on principles, requirements, and practices used to establish and implement an effective quality assurance program. The updated Guide cancels DOE G 414.1-2A, DOE G 414.1-3, and DOE G 414.1-5, Administrative Change 1, dated September 27, 2011. This Guide is consistent with the current quality assurance Order, DOE O 414.1D.

1.5.8.3 DOE G 414.1-4. DOE G 414.1-4 provides acceptable methods for implementing the safety software quality assurance requirements.

1.5.8.4 DOE G 413.3-2. DOE G 413.3-2 provides acceptable approaches for implementing quality assurance requirements related to the development and implementation of a quality assurance program. DOE G 413.3-2, Admin Change 1 was issued to incorporate an organizational name change.

1.5.9 DOE Action Plan

In July 2005, the DOE published an action plan[8] addressing ten lessons learned from the NASA Columbia Space Shuttle catastrophe of February 2003 and Davis–Besse[9] 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 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.

(a) *Operating Experience.* Individuals and organizations need to learn lessons from operating experience to avoid repeating errors and improve performance.

(b) *External Pressures.* Budget and schedule priorities must not override safe and reliable operation decisions.

(c) *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.

[8] DOE Action Plan, Lessons Learned from the Columbia Space Shuttle Accident and Davis–Besse Reactor Pressure Vessel-Head Corrosion Event, July 2005, is available at https://ehss.energy.gov/deprep/2005/TB05L29F.PDF.

[9] Refers to the Davis–Besse Nuclear Power Station, Oak Harbor, OH.

(d) Technical Inquisitiveness. Managers need to encourage employees to freely communicate safety and quality concerns and differing professional opinions.

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

(f) Normalizing Deviations. Routine departures from established standards should not be allowed to create a low-probability event to occur.

1.5.10 DOE EM-QA-001

The DOE Office of Environmental Management (EM) issued EM-QA-001in 2008, which requires contractors (at all levels) supporting DOE EM activities to develop quality assurance programs that comply with all Parts of ASME NQA-1–2004. EM-QA-001 was revised in 2012 to require consideration of ASME NQA-1a–2009 as well.

Section 2
AEC and NRC Regulations

2.1 SCOPE

This Section describes regulatory initiatives of the AEC and subsequently the NRC 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 C.F.R. 50, Appendix B, with other quality assurance-related regulations such as 10 C.F.R. 70, 71, and 72.

2.2 EARLY NUCLEAR POWER PLANTS

Recognition of the need for, and the adoption of, effective quality assurance regulations and standards, and guidance on the implementation of the regulations and standards, did not come rapidly to designers, constructors, operators, and 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 simple in their design, construction, and operation practices when compared to some later plants. 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 the constructed nuclear plants were formally turned over to them for operation. Most utilities were focused on producing electricity and, aside from cost considerations, did not really care whether the plant was run on coal, oil, gas, hydroelectric power, or nuclear power. Furthermore, except for applying the quality assurance provisions of the ASME BPVC, had little interest in developing and applying unique quality assurance standards per se for 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.[1] 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 1 yr 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 more fully recognized, it became apparent that a more systematic, disciplined, engineered approach to ensuring quality in nuclear facilities was needed.

Attempts were made as early as 1965 to bring a more robust quality assurance program into the industry, but it was not until the 1970s that the need was fully appreciated.

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. The rapid increase in size complexity and number of nuclear projects conclusively demonstrated that the nuclear industry and the AEC had no option but to pay the price for more exacting quality standards and regulations and they must institute 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

(a) developing quality assurance regulations and safety guides

[1] Address by Vice Admiral 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, DC, March 14 and 15, 1967.

(b) implementing the broad definition of quality assurance expressed by Commissioner Ramey that transcended the traditional manufacturing quality control and inspection concepts

(c) providing leadership and financial and technical assistance to an infrastructure dedicated to developing urgently needed national consensus quality assurance standards

2.2.1 10 C.F.R 50, Appendix A[2]

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 C.F.R. 50. 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, as follows:

(a) identification, evaluation, and use of appropriate quality standards

(b) a quality assurance program to ensure that structures, systems, and components perform their safety functions

(c) maintenance of appropriate records

Unit 2 at the Dresden Generating Station, Dresden IL, was the first nuclear power plant to be governed by 10 C.F.R. 50, Appendix A.

One might have argued that together the three fundamental requirements of Criterion 1 of 10 C.F.R. 50, Appendix A, were sufficient regulation for quality assurance in the design and construction of nuclear power plants; however, previous inspections and audits at commercial nuclear power plants belied that argument. They had 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

For example, AEC inspections at the Oyster Creek Nuclear Generating Station in Forked River, NJ, found continuing quality-related problems in control rod drives and steam separator, and cracks in the core shroud and supports. At the Big Rock Point Nuclear Power Plant in Charlevoix, MI, AEC inspectors found defects in fuel-assembly welds. At the R. E. Ginna Nuclear Power Plant in Ontario, NY, 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 implementation procedures or the lack thereof were not a major licensing issue of the AEC, the Advisory Committee for Reactor Safety (ACRS), and the Atomic Safety and Licensing Board (ASLB) at construction permit (CP) hearings.

Eventually, it became apparent to the AEC 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 beyond those in 10 C.F.R., Appendix A, and guidance on their application were needed. More importantly, a major paradigm shift was needed to counter a construction management attitude of "If the AEC inspector did not find a quality problem, it doesn't exist and need not be reported."

2.2.2 Zion Station Hearings Impact

On September 17, 1968, the lack of definitive quality assurance regulations, standards, and guidance caused the ASLB to suspend public hearings on Units 1 and 2 of Commonwealth Edison's (ComEd) Zion, IL, nuclear power station. The ASLB refused to issue a CP, stating

> In the opinion of the Board, however, 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 staff submitted evidence by way of criteria or expert testimony adequate to permit a judgment of its evaluation of the quality control program.[3]

The ASLB members who presided over the public hearings were S. Jensch, J. Buck, and S. Forbes.

Notwithstanding the ACRS asking about but receiving no commitment on methods of quality control during its 1967 CP review for Units 3 and 4 of the Turkey Point Nuclear Generating Station in Homestead, FL, the Zion hearing suspension was a watershed event in the history of nuclear power for quality assurance programs, commitment, requirements, and eventually regulation in the United States. It gave the highest visibility to the development and enforcement of quality assurance program regulations and standards against which the regulatory

[2] Paragraph 2.2.1 was contributed by Doug Brown, former Chair and current member of the ASME NQA Committee, and member of the ASME Board of Nuclear Codes and Standards.

[3] Nuclear Safety (March–April 1969), Vol. 10, No. 2, p. 194.

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 Corp. in Sacramento, CA, to develop a quality plan and procedures. Concurrently, Wilbur (Bill) Morrison[4] of the AEC Division of Reactor Standards (DRS) and Gene Langston of AEC RDT were tasked by the DRS Director to begin developing a set of quality assurance program criteria on which to judge the adequacy of ComEd's Zion Station quality assurance program. Morrison and Langston extracted applicable provisions from MIL-Q-9858A, RDT F2-2T, and NASA quality assurance documents into a series of draft DRS nuclear power plant quality assurance criteria. The first draft, dated October 3, 1968, included 16 criteria, A to P. The second draft, dated November 12 through 20, 1968, added purpose, definitions, program, control of special processes, mandatory inspection hold points, and test control.

On November 26, 1968, an 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 ComEd's quality assurance program for the Zion reactors.[5] Attending the meeting held in Bethesda, MD, were Chuck Long, Director of Reactor Licensing; Bill Morrison, DRS; Gene Langston, Reactor Development Technology Division (RDT); Harry Thornburg, compliance officer; Gerry Hadlock, Office of General Counsel.

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

When the ASLB reconvened hearings on December 17, 1968, one ASLB member 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 they thought it doubtful.

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

(a) ComEd's quality assurance program had not been very formal or well documented prior to this becoming an issue before the ASLB.

(b) 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 ASLB.

(c) 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, and after evaluating the plan against the 15 draft AEC quality assurance criteria, the AEC staff concluded that ComEd had developed and documented a philosophically acceptable quality assurance plan.[6] The CP was issued to ComEd for the Zion Station.

(d) It was recognized, however, that

(1) the plan had not been fully implemented

(2) some quality assurance elements had not been fully investigated

(3) changes to the plan and implementing processes and procedures would be needed as experience in their implementation was gained

(e) ComEd committed, albeit reluctantly, to fully implement the Zion Quality Assurance Plan by having all contractors working in the site by January 1, 1969, and implementing procedures by February 1, 1969.

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.

2.2.3 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 C.F.R. 50, Appendix B, adopted the following more encompassing definition of quality assurance, which was a slightly modified version of AEC Commissioner Ramey's definition: "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, that construction is performed to the design, and that the plant is operated and maintained within safe limits established by the design.

2.2.4 10 C.F.R. 50, Appendix B

Following the Zion Station hearings of the ASLB on December 17, 1968, representatives of the AEC DRS and RDT staff continued to develop the quality assurance

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

[5] Minutes of Commonwealth Edison Co.'s Zion Reactors prehearing inspection meeting held on November 26, 1968.

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

program criteria for nuclear power plants. Criteria were added and modified for the control of special processes and design, inspection and test, and other quality-affecting activities. The list of criteria grew to 21 and finally stabilized at 18.

On January 3, 1969, the DRS Director submitted to the ACRS for its 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, and Al Squires.

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

The AEC commissioners' completed their review on March 24, 1969. On April 17, 1969, the AEC published the proposed 18 quality assurance criteria of 10 C.F.R., Appendix B, in the Federal Register for public comment.[7]

The proposed AEC 10 C.F.R. 50, Appendix B, would require license applicants to include in their preliminary safety analysis report (PSAR) a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of structures, systems, and components of the facility. It also would require that the final safety analysis report contain information concerning measures to be taken to ensure safe operation of the facility, including 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.

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

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 section headings, 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 made the following changes to the proposed quality assurance criteria of 10 C.F.R. 50, Appendix B:[8]

(a) *Section III, Design Control*. This section was extensively revised "to (a) require provisions to assure that appropriate quality standards are included in design documents and that deviations from such standards are controlled; (b) require that measures be established for the selection and review for suitability of application of materials, parts, equipment, and processes; (c) indicate that design control measures may include means 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."

(b) *Section IV, Procurement Document Control*. This section was modified "to recognize that all sections of the quality assurance criteria may not be applicable to all contractors or subcontractors."

(c) *Section V, Instructions, Procedures, and Drawings*. This section was revised "to make clear that the criteria for determining that important operations have been satisfactorily accomplished need not be duplicated on more than one design document."

(d) *Section VII, Control of Purchased Material, Equipment, and Services.* This section was expanded "to require that documentary evidence that material and equipment conform to procurement requirements shall be available at the nuclear power plant site prior to installation or use."

[7] 34 Fed. Reg. 73 (April 17, 1969), pp. 6600–6602.

[8] Quotes in paras. 2.2.4(a) through 2.2.4(i) are from 35 Fed. Reg. 125 (June 27, 1970), p. 10498.

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

(f) Section X, Inspection. This section was revised "(a) to eliminate the implication that in-process inspection and mandatory inspection 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."

(g) Section XIV, Inspection, Test, and Operating Status. The requirement for marking nonconforming items was deleted "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."

(h) Section XVI, Corrective Action. This section 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 initial inspection. The requirement that the cause be determined and corrected to preclude repetition was changed "to apply to significant conditions adverse to quality."

(i) Section XVIII, Audits. To avoid the implication that personnel performing audits should be qualified to specified requirements, the term "appropriately 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.[9] 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 than it really was.

Nevertheless, Case believed there were important quality assurance elements that were not being applied routinely to the design. 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 C.F.R. 50, Appendix B, was issued as a regulation in June 1970,[10] only 12 nuclear power plants had operating licenses; numerous other plants were in varying stages of their applications for CPs and operating licenses. Therefore, older plants had no commitment in their licensing applications to implement the proposed quality assurance criteria of 10 C.F.R. 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 C.F.R. 50, Appendix B, for the previously licensed nuclear power plants.

When 10 C.F.R. §50.34(a)(7) became mandatory in 1970, it required an applicant for a license to submit a description of its quality assurance program per the criteria of 10 C.F.R. 50, Appendix B, for the design and construction phase in a section of the 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 CP.

Parallel to the regulatory effort, the ANSI N45 Subcommittee developed and published ANSI N45.2-1971. This standard gave general requirements for a quality assurance program. In June 1972, the AEC issued Safety Guide 28 endorsing the ANSI standard, which was an important step forward in providing guidance to the industry on how to develop and enact a program that would meet the regulatory requirements. This also provided a level of uniformity in application contents.

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 CP.

The ASLB prompted this action during the March 1973 public licensing hearings for Consumer Power's Midland, MI, station 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."[11]

The ASLB decided that the AEC staff must do more than a simple desktop review of the applicant's quality assurance program to determine whether the requirements of 10 C.F.R. 50, Appendix B, were met and were being implemented.

Regarding scope, the introduction to 10 C.F.R. 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

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

[10] 35 Fed. Reg. 125 (June 27, 1970), pp. 10498–10501.

[11] RAI-73-1 (January 1973), p. 184.

Table 2.2.4-1 Comparison of DOD MIL-Q-9858A, NASA NHB 5300.4(1B), and 10 C.F.R. 50, Appendix B

DOD MIL-Q-9858A Quality Program Requirements		NASA NHB 5300.4(1B) Quality Program Provisions for Aeronautical and Space System Contractors	10 C.F.R. 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 1B200, General 1B202, Training	II	Quality Assurance Program
3.3	Work Instructions	1B203, Quality Information 1B300, Technical Document	V VI	Instructions, Procedures, and Drawings Document Control
	...	Chapter 3, Design and Development Controls 1B300, Technical Documents 1B302, Change Control	III	Design Control
3.4	Records	1B405, Data Retrieval 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 5.1 5.2	Control of Purchases Responsibility Purchasing Data	Chapter 5, Procurement Control 1B501, Selection of Contractor Procurement Sources 1B502, Procurement Documents	IV VII	Procurement Document Control Control of Purchased Equipment and Services
6.1	Materials and Material Control	Chapter 4, Identification and Data Retrieval	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 XI	Inspection Test Control
6.4	Handling, Storage and Delivery	Chapter 11, Handling, Storage, Etc	XIII	Handling, Storage and Shipping
6.5	Nonconforming Material	Chapter 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 Program Audits	XVIII	Audits

including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

See Table 2.2.4-1 for a comparison of 10 C.F.R. 50, Appendix B, with MIL-Q-9858 and NASA NHB 5300.4(1B).

2.2.4.1 Fuel-Reprocessing Plants. On March 8, 1971,[12] the AEC Director of Regulation proposed to the Secretary of the AEC an amendment to 10 C.F.R. 50, Appendix B, that would extend to fuel-processing plants the same requirements as for nuclear power plants. The amendment had been requested by the DRS Director. The requirements would apply to the design, construction, and operation of those structures, systems, and components of fuel-processing plants that prevent or mitigate the consequences of accidents which could cause undue risk to the health and safety of the public.

The title of 10 C.F.R. 50, Appendix B, was changed to "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."[13]

[12] 36 Fed. Reg. 70 (April 10, 1971), pp. 6903–6904.

[13] 36 Fed. Reg. 177 (September 11, 1971), p. 18301.

The AEC Division of Compliance and Office of General Counsel concurred in this proposed amendment. RDT also concurred in this recommendation with the comment that RDT expected that the AEC rules would be further amended to apply these same quality assurance requirements to plutonium processing and fabrication plants subject to licensing requirements similar to those for reactors and reprocessing plants. This comment would later be taken into account in the development of a proposed amendment to 10 C.F.R. 70 to provide for preconstruction review of plutonium processing and fabrication plants.

The development of quality assurance standards was not always clean or direct. In parallel with the development of 10 C.F.R. 50, Appendix B, and ANSI N45, ANS Committee 3 developed what would become ANSI N18.7-1972, which focused more on the requirements after the plant entered operations. This standard was also endorsed by the NRC in its Safety Guide 33, issued in August 1972. It was obvious that the two groups shared a common goal; attaining the goal would require ongoing effort in coordination.

2.2.4.2 Amendment to Criterion I of 10 C.F.R. 50, Appendix B. On April 19, 1974, the AEC Director of Regulation proposed a rule change to Criterion I, Organization, of 10 C.F.R. 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 the nuclear field. In addition, because of significant changes in the management arrangements under which nuclear power plants were being built, organizations with limited nuclear experience were undertaking project management functions. To assist applicants and licensees in the development and implementation of their quality assurance programs, the AEC decided to supplement Criterion I with more detailed quality assurance requirements. In developing these requirements, the AEC took into account the experience accumulated in designing, constructing, and operating licensed nuclear power plants and AEC-owned reactors.

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

2.3 ASME NQA-1

As mentioned earlier, there were multiple parallel developments in quality assurance. The parallel and sometimes conflicting guidance created confusion among the users and frustration in all who were concerned with attaining and assuring quality. During the late 1970s, in an effort to reduce the confusion and increase the usability of the standards, ASME consolidated at least seven standards into one: ANSI/ASME NQA-1. Published July 24, 1979, ANSI/ASME NQA-1 was a significant step forward in simplifying the documentation providing guidance to nuclear license holders. However, as was expected, the consolidation of so many discrete documents into a single standard generated many comments and public feedback. This, combined with the growing list of lessons learned from the Three Mile Island incident, led to the need for a revision to address all the concerns. A revised ANSI/ASME NQA-1 was published in 1983.

ANSI/ASME NQA-1 (later redesignated ASME NQA-1) was an attempt to consolidate all quality assurance programs guidance for all phases of a nuclear project into one standard. However, in NRC Regulatory Guide 1.28,[14] the NRC endorsed that program only for design and construction. It was anticipated that the operational portions would be endorsed by a revision to NRC Regulatory Guide 1.33, but such a revision was not issued.

The NRC did, however, incorporate ASME NQA-1 into 10 C.F.R. §50.55a by reference. An important point to remember is that a previously issued license is not affected by this change to the regulations. The ASME NQA-1 program was modeled on the 18 criteria of 10 C.F.R. 50, Appendix B. Through its use of sections, ASME NQA-1 combines requirements and guidance into one standard.

2.4 FORD AMENDMENT STUDY (NUREG-1055)

In 1984, the NRC reported on a major study undertaken 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 comprised case studies of quality assurance failures that occurred in the construction projects for the Diablo Canyon Power Plant in San Luis Obispo, CA; Marble Hill Nuclear Power Station in Marble Hill, IN; South Texas Nuclear Generating Station in Bay City, TX; and William H. Zimmer Power Station in Moscow, OH. Major quality-related problems that contributed to the failures at

[14] With the change from AEC to NRC in 1975, Safety Guides became Regulatory Guides. The existing Safety Guide numerical designators were updated with a "1." prefix; e.g., AEC Safety Guide 28 became NRC Regulatory Guide 1.28.

these sites might have been avoided had the project managers and the NRC 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.

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

According to this study, the following quality-related principles are essential to a successfully managed commercial nuclear power plant project:

(a) Top-down project management commitment to quality is a principal project objective.

(b) Top management understands the magnitude, complexity, and difficulties of designing and constructing a nuclear power plant as opposed to a conventional steam plant, and the importance of applying exacting engineering and quality standards.

(c) Key project personnel have prior nuclear facility design and construction experience.

(d) Quality assurance is implemented as an integral part of a comprehensive management control system.

(e) Quality problems in design are promptly detected, communicated, and corrected; design processes have effective oversight; and plant configuration is controlled and managed.

2.5 CONTINUED OPERATION, 1980s TO PRESENT

During the 1980s and 1990s, nuclear construction projects were reaching completion or were being abandoned. The Ford Amendment Study triggered a great deal of activity as the NRC and industry attempted to address the issues identified, post–Three Mile Island.

As the knowledge and experience in NQA programs developed, ASME NQA-1 was revised to reflect this growing knowledge. The newer editions of the Standard were not endorsed via NRC Regulatory revision. The early revisions to ASME NQA-1 through the 1992 addenda that the NRC found acceptable were incorporated into 10 C.F.R. §50.55a, which a licensee can choose to adopt. If the licensee does not voluntarily choose to revise their license and update their program to these new revisions of the regulations, the revisions have no effect on them. A more detailed discussion of the development and history of the ASME and ANS standards can be found in Section 5.

During this period, operating plants experienced a dramatic increase in capacity factor: from near 50% in 1980 to approximately 90% in the late 1990s and early 2000s. Concurrent with that, there was a significant reduction in unplanned shutdowns.[15] Effective quality assurance programs that conformed to the regulations are considered to be one factor in that success. Consequently, the NRC has not revised the regulations governing quality assurance programs.[16] Industry has developed programs that meet the requirements, and those requirements are not lacking in serving and protecting the public.

2.6 NEW CONSTRUCTION IN THE 2000s

As new construction loomed in the early 2000s, the NRC reviewed many of its Regulatory Guides to ensure they were current. NRC Regulatory Guide 1.28 and NRC Regulatory Guide 1.33 were both revised to reflect the current state of the endorsed standards. NRC Regulatory Guide 1.33, Revision 3, issued in June 2013, endorsed ANS 3.2-2012, with some exceptions. NRC Regulatory Guide 1.28, Revision 5, issued in October 2017, endorsed ASME NQA-1b–2011, ASME NQA-1–2012, and ASME NQA-1–2015, subject to conditions outlined in the NRC Regulatory Guide. The NRC considered revising 10 C.F.R. 50, Appendix B, but ultimately decided not to.

Although often criticized as being too prescriptive and not sufficiently performance based, 10 C.F.R. 50, Appendix B, has withstood the test of time during the nearly 50 yr of its application. Since its adoption by the industry, the operational record of nuclear plants is unrivaled.

[15] These and other statistics on nuclear power generation in the United States are available from the Nuclear Energy Institute (www.nei.org/resources/statistics).

[16] The NRC revised 10 C.F.R. 50, Appendix B, in 2007 to coordinate with changes in 10 C.F.R. 52. The quality assurance program requirements did not change.

Section 3
ANSI/ASME N45.2 and Associated Standards

3.1 SCOPE

This Section describes the development of ANSI/ASME N45.2 and its supplemental "daughter" standards, issued from 1969 to 1977; the AEC "Rainbow" series of guidance documents; and the safety and regulatory guides that endorsed the ANSI/ASME N45.2 series of standards.

3.2 RECOGNITION OF THE NEED FOR STANDARDS

By the late 1960s, it had become 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. The national consensus standards process of the American National Standards Institute (ANSI) would permit experts from government, industry, national laboratories, and other public institutions to contribute to the definition of these practices.

With financial backing, significant participation, and strong endorsement from the AEC and industry leadership, a plan for a whole body of urgently needed national consensus standards was formulated. The 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 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:

(a) pressure system cleaning

(b) packaging, shipping, receiving, handling, storage

(c) housekeeping (total plant)

(d) installation, inspection, and testing — electrical and instrumentation

(e) inspection and testing — structural steel and structural concrete

(f) qualification of personnel

(g) quality assurance program requirements

Six of the 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 BPVC. 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.

3.3 ANSI N45.2-1971

During a meeting at Commonwealth Edison in May 1969, the ANSI N45 Committee established the ad hoc ANSI N45-3.70 Committee 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 ANSI N45-3.70 Committee was composed of representatives from the AEC and its national laboratories and key segments of the nuclear industry, including utilities, reactor suppliers, plant engineers, and constructors.

The initial activities of the ANSI N45-3.70 Committee focused on a critical review of the draft 10 C.F.R. 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, it was 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 C.F.R. 50, Appendix B. To expedite the development process, an editorial team within the committee was formed and members of the committee were asked to submit their individual suggestions to the editorial team on the content of the standard. The team then met in Santa Barbara, CA, for an intensive four-day series of sessions to incorporate input from the committee members into a coherent document. The resulting draft included practically all of the material submitted by the committee contributors and was unanimously accepted by the committee with minimal change.

In August 1970, a new ANSI 45-3 Subcommittee on Nuclear Quality Assurance Standards was formed to consolidate this draft 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. Prior to publication, the ANSI standard number was changed first 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 subsequently by the ANSI Board of Standards Review in October 1971. ANSI N45.2-1971 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 N45.2. The structure and content of the standard were as follows:

1 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 Procurement 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 Corrective Actions
18 Quality Assurance Records
19 Audits

ANSI N45.2-1971 set forth the requirements and guidance for planning, managing, and implementing overall quality assurance programs for nuclear power plants. These general requirements applied to all phases of the quality assurance program and to the total power plant whereas 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 requirements and the 10 C.F.R. 50, Appendix B, criteria was in their degree of specificity, which fundamentally supports the reason why ANSI N45.2 was developed: it contained supplemental requirements and guidance on quality assurance. 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 ANSI N45.2 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 nonregulatory situations.

Concurrent with the development and publication of ANSI N45.2-1971, other N45 ad hoc committees were developing a series of standards that set forth more detailed requirements for certain activities to ensure quality of nuclear power plants. These requirements were to be coordinated with the requirements of ANSI N45.2-1971. In September 1971, these ad hoc committees became working groups. In November 1971, these working groups were developing the work practice standards listed in Table 3.3-1.

3.4 ASQC MATRIX

In October 1973, the Interface Committee of the American Society for Quality Control (ASQC) Nuclear Power Technical Committee met in Groton, CT, 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 C.F.R. 50, Appendix B; ANSI N45.2-1971; ASME BPVC, 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, and 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

Table 3.3-1 ANSI Work Practice Standards in Development in 1971

ANSI Working Group	Standard in Development in 1971	
	Designator	Title
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 (During the Construction Phase)
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

training in quality standards and regulations and interfacing with technical societies.

3.5 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 ANSI N45.2-1971 in AEC Safety Guide 28 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 they permitted positive findings relative to the licensing process.

3.6 ANSI N45.2 “DAUGHTER” STANDARDS[1]

After sponsoring the development of ANSI N45.2 and the N45 working groups' initial drafts of ANSI N45.2.1 through ANSI N45.2.10, the ANSI N45 Committee 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 N45 Committee and for the development of other quality assurance-related standards.

The ANSI N45-3 Subcommittee comprised members of the previous ANSI N45-3.7 Subcommittee and N45 ad hoc working groups 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 ASQC. For example, the IEEE Joint Committee of Nuclear Power Standards (JCNPS) prepared 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 N45.2.4. Furthermore, ASCE developed a standard covering installation and inspection of civil/structural items that was approved by the ANSI N45 Committee and became ANSI N45.2.5.

It was recognized that users of ANSI N45.2 and its associated work practice standards would need supplemental requirements and nonmandatory guidance to effectively implement the basic ANSI 45.2 quality assurance program requirements in certain key quality-affecting areas. These key areas are discussed in the following paragraphs:

[1] Subsection 3.6 was contributed by Sidney Bernsen, former Chair of the ASME N45-2 Subcommittee and former member of the ASME NQA Committee.

(a) Design. Although Requirement 3 of ANSI N45.2-1971 included basic requirements for the assurance of quality in the design of nuclear power plants, the AEC and industry recognized that more specificity was needed. The ANSI N45-2 Subcommittee formed a working group composed primarily of senior design managers to describe realistic design control practices for nuclear power plants. This effort resulted in ANSI N45.2.11.

(b) Procurement. To address the need for quality assurance requirements specific to the procurement of items for nuclear power plants, the ANSI N45-2 Subcommittee formed a working group consisting of individuals with extensive experience in procurement and shop-inspection practices. This group developed ANSI N45.2.13.

(c) Auditing and Auditor Qualification. The desire among members of the industry to share audits was a principal driver for the development of additional requirements and guidance on the performance of audits and the qualification of auditors. Once again, the ANSI N45-2 Subcommittee selected highly experienced individuals from industry, national laboratories, and government to develop two documents: ANSI/ASME N45.2.12 for auditing quality assurance programs for nuclear power plants and ANSI/ASME N45.2.23 for qualification of auditors.

(d) 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 would be 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 ANSI/ASME N45.2.9.

The ANSI N45-2 Subcommittee's careful management ensured that this suite of needed standards was completed on an expedited schedule. The subcommittee's success demonstrated the value of having a single organization oversee the development of related standards.

Consequently, 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 ANSI N45-2 Subcommittee assumed the position of area manager for nuclear quality assurance standards, which led to the formation of a smaller advisory group within the subcommittee.

The supplemental quality assurance standards became known as daughter standards to ANSI N45.2. ANSI N45.2 daughter standards consisted of two basic types: those that amplified the programmatic aspects of ANSI N45.2 and those that focused on quality-related work practices.

The seven ANSI N45.2 programmatic daughter standards and the corresponding NRC Regulatory Guides that endorsed them are listed in Table 3.6-1.

Each of the standards issued by the ANSI N45-2 Subcommittee was subjected to an intensive preparation and review process to ensure that it 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 C.F.R. 50, Appendix B.

3.7 AEC RAINBOW SERIES

In the early 1970s, the nuclear industry's implementation of the quality assurance criteria of 10 C.F.R. 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 ANSI N45.2 quality assurance program in compliance with 10 C.F.R. 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 issue 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 phases of nuclear power plant construction. With the concurrence of the N45 Standards Committee, the Gray Book included the pertinent ANSI 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 nationwide to discuss the contents of the Gray Book.

In October 1973, the AEC regulatory staff issued the second in the series of guidance documents, 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 documents, known as the Green Book (WASH-1309), was issued and a final series of regional

Table 3.6-1 ANSI N45.2 Daughter Standards and Corresponding NRC Regulatory Guides

ANSI N45.2 Daughter Standard		Corresponding NRC Regulatory Guide
Designator	Title	
ANSI/ASME N45.2.6-1978	Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants	1.58
ANSI/ASME N45.2.9-1979	Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants	1.88
ANSI N45.2.10-1973	Quality Assurance Terms and Definitions	1.74
ANSI N45.2.11-1974	Quality Assurance Requirements for the Design of Nuclear Power Plants	1.64
ANSI/ASME N45.2.12-1977	Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants	1.144
ANSI N45.2.13-1976	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants	1.123
ANSI/ASME N45.2.23-1978	Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants	1.146

conferences was held to discuss quality assurance during the construction phase of nuclear power plants.

It is significant that an underlying theme of the Rainbow Series was the AEC's encouragement to industry to use applicable national consensus standards, particularly ANSI N45.2 and its daughter standards, some of which were recognized as being appropriate even in draft form, to meet the criteria of 10 C.F.R. 50, Appendix B. The ANSI N45-3 Subcommittee was pleased with the sustained participation of Bill Morrison of the NRC and the timely support of the AEC commissioners, directors of reactor standards and licensing, and their staffs.

3.8 ANSI/ASME N45.2–1977

The N45 Committee was an American National Standards Committee operating 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 ANSI/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, ASME revised ANSI N45.2. The new edition, ANSI/ASME N45.2-1977, had a broader scope than its predecessor and a new title, "Quality Assurance Program Requirements for Nuclear Facilities." These changes provided for the application of ANSI/ASME N45.2 to nuclear facilities for power generation, spent nuclear fuel storage, fuel reprocessing, and plutonium processing and fuel fabrication. These changes were also consistent with the NRC's extending the applicability of 10 C.F.R. 50, Appendix B, to 10 C.F.R. 70, which applies to fuel-reprocessing facilities.

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

(a) qualifications of inspection and test personnel
(b) quality assurance records retention times
(c) internal and external quality assurance program audits

Section 4
ASME NQA-1 and Related Standards

4.1 SCOPE

This Section describes the evolution of ASME NQA-1 and ANSI's "N" quality assurance program standards, the consolidation of the ASME N45.2 work practice standards and ASME NQA-1, and the restructuring of the ASME NQA standards from 1979 to 2004.

4.2 ANSI "N" COMMITTEE STANDARDS

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

4.2.1 ANSI/ANS 3.2 and ANS N18.7[1]

Preparation of the first edition ANSI/ANS 3.2 began 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 ANSI 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 N45.2-1971. Because of this dual NRC endorsement, the ANS 3.2 and ANSI 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 accident at Three Mile Island's Unit 2 in 1979, ANS revised ANSI 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 (see para. 4.3.1), which had superseded several of the ANSI N45.2 daughter standards that had been referenced in ANSI N18.7-1976. NRC Regulatory Guide 1.33, Revision 2, dated February 1978, endorsed this revision.

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

4.2.2 ANSI N46.2 Standards

Paralleling the development of the ANSI N45.2 standards, the ANSI 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 ANSI N46.2-1978 for post-reactor nuclear fuel-cycle facilities as an American National Standard. By joint agreement between ASME and AIChE to use ANSI N45.2, ANSI N46.2 was withdrawn.

4.3 ASME NQA COMMITTEE

Recognizing the need to minimize redundancy in similar requirements and to more clearly define the 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 ANSI N45.2 standards, to the ANSI 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, provided these procedures met ANSI consensus requirements. Each organization could then submit its standards to ANSI for 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, ASME formed the ASME Board of Nuclear Codes and Standards to manage ASME nuclear standards efforts. In October

[1] Paragraph 4.2.1 was contributed by Charles Moseley, Jr., ASME NQA Committee member and ANS 3-2 Committee liaison.

1975, the ANSI N45 Committee transferred quality assurance standards responsibility to a newly constituted ASME Committee on Nuclear Quality Assurance (NQA).

4.3.1 ANSI/ASME NQA-1–1979

Because different ANSI N45-3 working groups had developed numerous interrelated ANSI 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 ANSI 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 standard.

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

The need to consolidate the ANSI N45.2 series of standards was also firmly supported by ASME as a means for amplifying the quality assurance provisions of the ASME BPVC 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 ANSI/ASME N45.2-1977 and the seven ANSI N45.2 daughter standards listed in Table 3.6-1 into a single standard. Toward this objective, the new ASME NQA Committee adopted the following approach to consolidation:

(a) The 18 criteria of 10 C.F.R. 50, Appendix B, would be preserved as basic requirements.

(b) These basic requirements would provide an overview of the quality assurance program logic and would be sufficiently general to have wide applicability.

(c) More specific, detailed requirements would be contained in supplements.

(d) Requirements would be clearly separated from guidance, the latter being relocated to nonmandatory appendices.

(e) The full expertise of ASME and other standards-writing societies would be employed in developing, coordinating, and maintaining the standard.

(f) The standard would provide for flexibility in its application as well as growth or reduction of supplementary requirements and guidance.

(g) Redundancy and conflicts in programmatic requirements would be minimized.

The standard would not be as limited to safety-related structures, systems components, and associated activities as 10 C.F.R. 50, Appendix B, 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 shown in Table 4.3.1-1, ASME NQA-1–1979 was structured as basic requirements, supplements, and appendices, per the ASME NQA Committee's intended approach [see (a) through (d)]. In addition, the basic requirements were reworded using clear and concise language, e.g., "The design shall be defined, controlled, and verified . . . ," instead of the obtuse language of 10 C.F.R. 50, Appendix B, e.g., "Measures shall be established to . . . ."

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

4.3.2 ANSI/ASME NQA-1–1983

In general, the ASME NQA Committee made only minor wording changes in the 1983 edition of ANSI/ASME NQA-1 and its two addenda.[2] However, the revision of the phrase "nuclear power plants" to "nuclear facilities" in this edition, while seemingly subtle, significantly expanded the usability and applicability of the standard.[3]

In August 1985, the NRC endorsed ANSI/ASME NQA-1–1983 in NRC Regulatory Guide 1.28, Revision 3, with only three regulatory positions. These regulatory positions concerned the qualification of inspection, test, and nondestructive examination personnel; quality assurance records; and audit frequency. While the NRC has not consistently endorsed successive editions of ASME NQA-1 (see para. 4.3.12), several licensees have had their quality assurance programs approved to more recent editions.

4.3.3 ANSI/ASME NQA-1–1986

The ASME NQA Committee issued ANSI/ASME NQA-1–1986 and its three addenda[4] with relatively minor editorial changes.

4.3.4 ANSI/ASME NQA-2

The ASME NQA Committee developed ASME NQA-2 to incorporate the seven ANSI/ASME N45.2 daughter standards into a single standard (see Table 4.3.4-1). Following the first edition, ANSI/ASME NQA.2–1983, the standard was revised eight times from 1983 to 1991.

[2] ASME NQA-1a–1983 was issued December 31, 1983, and ASME NQA-1b–1984 was issued March 15, 1985.

[3] This evolution, and modification, as related to ASME NQA-2 did not occur until 1986.

[4] ASME NQA-1–1986 was issued July 11, 1986; ASME NQA-1a–1986, February 15, 1997; ASME NQA-1b–1987, March 15, 1988; and ASME NQA-1c–1988, February 28, 1989.

The following additional quality assurance work practice standards were incorporated as Parts into ANSI/ASME NQA-2–1986, ASME NQA-2–1989, and their addenda:

Part 2.4 Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities (incorporated by reference to ANSI/IEEE Std 336-1985)

Part 2.7 Quality Assurance Requirements of Computer Software for Nuclear Facility Applications

Part 2.16 Standard Requirements for Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities (incorporated by reference to ANSI/IEEE Std 498-1985, subsequently canceled)

Part 2.18 Quality Assurance Requirements for Maintenance of Nuclear Facilities

Referencing parts of ASME 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., ANSI/IEEE Std 498), ASME N45.2 was left without a valid reference.

4.3.5 ASME NQA-1–1989

In the 1989 edition of ASME NQA-1, the ASME NQA Committee extended the standard's scope to include siting and decommissioning of nuclear facilities. It also clarified or amplified certain supplementary requirements, such as those for design control and document control. Addenda to the 1989 edition were issued in 1990, 1991, and 1992.

Table 4.3.1-1 Structure of ANSI/ASME NQA-1–1979

Basic Requirements		Supplements		Appendices	
1	Organization	1S-1	Organization	1A-1	Organization
2	Quality Assurance Program	2S-1	Qualification of Inspection and Test Personnel	2A-1	Qualifications of Inspection and Test Personnel
		2S-2	Qualification of Nondestructive Examination Personnel	2A-2	Quality Assurance Programs
		2S-3	Qualification of Quality Assurance Program Audit Personnel	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		...		...
17	Quality Assurance Records	17S-1	Quality Assurance Records	17A-1	Quality Assurance Records
18	Audits	18S-1	Audits	18A-1	Audits

Table 4.3.4-1 ANSI/ASME N45.2 Daughter Standards Incorporated Into ANSI/ASME NQA-2

ANSI/ASME N45.2 Daughter Standard		Corresponding Part in ANSI/ASME NQA-2
Designator	Title	
ANSI/ASME N45.2.1-1980	Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants	2.1
ANSI/ASME N45.2.2-1978	Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants (During the Construction Phase)	2.2
ANSI N45.2.3-1973	Housekeeping During the Construction Phase of Nuclear Power Plants	2.3
ANSI/ASME N45.2.5-1978	Construction Phase Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel for Nuclear Power Plants	2.5
ANSI/ASME N45.2.8-1975	Quality Assurance Requirements During Installation, Inspection and Testing of Mechanical Equipment and Piping for the Construction Phase of Nuclear Power Plants	2.8
ANSI/ASME N45.2.15-1981	Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants	2.15
ANSI/ASME N45.2.20-1979	Supplementary Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants	2.20

4.3.6 ASME NQA-3–1989

Responding to an identified need, in 1984, the ASME NQA 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 ASME NQA-3–1989.

In addition to those activities affecting quality in ASME NQA-1, ASME NQA-3 contained basic requirements, supplements, and nonmandatory appendices on

(a) readiness reviews
(b) peer reviews
(c) data and sample management
(d) data collection and analysis
(e) coring
(f) sampling
(g) in situ testing
(h) scientific investigation
(i) design data process control

In restructuring and consolidating ASME NQA-1, ASME NQA-2, and ASME NQA-3 (see para. 4.3.7), the ASME NQA Committee was undecided about what to do with ASME NQA-3. The reason was that ASME NQA-3 was an application standard for which Part IV of ASME NQA-1 had not yet been established. Thus, according to its Foreword, ASME NQA-3–1989 guidance on the application of ASME 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 ASME NQA-1–2004, ASME NQA-3 was embedded in Part III, Subpart 3.3, as a nonmandatory appendix. Salient requirements of ASME NQA-3 have since been integrated into Parts I and II of ASME NQA-1.

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

4.3.7 ASME NQA-1–1994

In the early 1990s, ASME NQA Committee leadership concluded that ASME NQA-1, ASME NQA-2, and ASME NQA-3 were not structured in a way that enabled users to understand and apply these three standards. Thus, the ASME NQA Committee decided to consolidate ASME NQA-1 and ASME NQA-2 into a single multipart standard that would allow a more rapid response to varied applications of the ASME NQA requirements and guidance. The ASME NQA Committee restructured ASME NQA-1–1994 into the following three parts, and retitled it "Quality Assurance Requirements for Nuclear Facility Applications" to accommodate the inclusion of ASME NQA-2:

(a) Part I contained an introduction and basic quality assurance program requirements followed by supplementary requirements for nuclear facilities, all from the former ASME NQA-1.