DEFENSE NUCLEAR FACILITIES SAFETY BOARD

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March 26, 2001

The Honorable Spencer Abraham
Secretary of Energy
1000 Independence Avenue, SW
Washington, DC 20585-1000

Dear Secretary Abraham:

The Defense Nuclear Facilities Safety Board (Board) has on a number of occasions, during the past several years, urged the Department of Energy (DOE) to upgrade its programs for ensuring reliability and operability of structures, systems, and components serving vital nuclear safety functions at defense nuclear facilities. DOE's Quality Assurance (QA) program is central to that effort. Departmental assessments of the status and effectiveness of implementation are currently underway. The Board is planning a series of public meetings on the subject of nuclear quality assurance (NQA). The first is scheduled for March 28, 2001. Our objective is the gathering of information that may be useful in planning a path forward to enhance effectiveness of DOE's QA program.

Enclosed for consideration of those in DOE with nuclear safety responsibilities is technical report, DNFSB/TECH-31, Engineering Quality into Safety Systems. The executive summary provides a number of observations by Board member, Joseph DiNunno. These will be explored by the Board during these public meetings. The Board will be looking for the staff of DOE to participate in these sessions.

Sincerely,

John T. Conway
Chairman

c: Mr. Mark B. Whitaker, Jr.

DNFSB/TECH-31

ENGINEERING QUALITY INTO SAFETY SYSTEMS

Defense Nuclear Facilities Safety Board

Technical Report

March 2001

ENGINEERING QUALITY INTO SAFETY SYSTEMS

This report was prepared for the Defense Nuclear Facilities Safety Board by Board Member Joseph J. DiNunno.

PREFACE

Evidence exists in the form of Department of Energy (DOE) enforcement actions and Defense Nuclear Facilities Safety Board staff reports that the Quality Assurance program of DOE is not working as well as it should be. The question is, [W]hy not? The purpose of this report is to explore this matter and suggest directions for a revised path forward to improvement.

EXECUTIVE SUMMARY

In this report, various aspects of the Department of Energy's (DOE's) Quality Assurance (QA) program are addressed. A number of observations (see Section 3) are provided that might well be considered by DOE in further performing self-assessments of QA complex-wide and in structuring improvement programs. A summary of key observations is as follows:

- Whatever deficiencies exist in DOE's QA program, they are not due to a lack of contractors' program descriptions or procedural guidance. The problem is one of a failure to implement known good practices.

- A program to ensure high quality in the services and engineered systems required to ensure safety should not be made dependent upon the adaptation and successful implementation of Total Quality Management (TQM) concepts for the overall operation of DOE.

- The guidance currently contained in DOE Guide 414.1-2 is oriented much more toward the use of TQM than Nuclear Quality Assurance (NQA) for quality management. There is a disconnect between those who have fashioned the new rule and associated guides and those who are charged with implementing and/or enforcing them. This disconnect needs to be addressed.

- The area requiring principal attention by DOE relative to its contractors' NQA programs is the emphasis placed by contractor line managers on quality requirements in the design, procurement, fabrication, construction, and operation of vital safety systems.

- Integrated Safety Management (ISM) and NQA need to be treated as complementary functions and managed at the top by the same organizational entities. ISM is intended to instill a consistent way of planning and performing hazardous work. QA programs are intended to systematically define quality requirements for all activities related to this work and to make certain such requirements are satisfied in delivered products .

- The most important aspects of NQA that contractors need to address are: (1) how they plan to satisfy their responsibilities to ensure that the requisite quality-related specifications are defined for their safety-related products and services, and (2) how they will ensure that such quality specifications are subsequently satisfied in the products and services they provide to the government.

- Prequalifying vendors through certification or similar processes is a good practice but is not sufficient unto itself. Quality requirements need to be clearly defined for all services and products important to safety, and products received must be subject to sufficient incoming inspection so as to make certain that they conform to specifications.

- The functions and principles embodied in ISM have much in common with TQM concepts. Before DOE undertakes to expand its quality horizons to encompass all work products and services, it would do well to fully implement quality programs required to ensure the safety of its hazardous operations.

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1. INTRODUCTION

1.1 QUALITY OF ENGINEERED PRODUCTS

The design and construction of devices to perform tasks beyond the capabilities of the human body have occupied the mind and efforts of man since earliest times. Utility (serving a useful function) must have been the first criterion for judging success. If something did not work, it was abandoned. Reliability must have been the second criterion, for unless an "engineered" device (e.g., a spear, a sword, a gun, a boat, a boiler) could be depended on when called upon to work, its attempted use could be perilous. Safety of the user must certainly have been the third criterion, for otherwise man might have been destroyed by his own inventions. While advances in mathematics and science over the centuries have enabled the development of increasingly sophisticated engineering devices, utility, reliability, and safety remain the fundamental measures of acceptability. To these three one must pragmatically add a fourth—affordability. An engineered solution to a problem that cannot be afforded will not be used. The human race continues to test its inventions against these basic criteria.

The quality of an engineered product can be measured by the degree to which these four basic factors are evident in the product. Recognizing that high confidence in the safety of applications of radioactive materials was essential to social acceptance of such uses, the nuclear industry from its inception sought to ensure high quality in the systems, structures, and components upon which safe applications of nuclear materials depend. As discussed above, the objective was to achieve: (1) utility, (2) reliability, (3) safety, and (4) affordability. These measures of quality were to be achieved to a high degree. That achievement was found to be more likely if engineered products were subjected to disciplined design, procurement, fabrication, construction, and operational processes, and if the effectiveness of those processes was independently verified. Accordingly, a program of Quality Assurance (QA) evolves from two basic acts: (1) creating products through design and fabrication processes that make for high quality (Quality Control [QC]), and (2) auditing such processes to confirm that they have been well executed and that they have been effecting in achieving the required quality.

1.2 QUALITY ACHIEVEMENT: A POINT AT ISSUE

The Department Energy (DOE) requires its contractors by rule and contract provisions to implement QA programs in the performance of their work. Rule requirements are set forth in 10 C.F.R. § 830.120.[1] When specified by contract, requirements defined in DOE Order 414.1A are made applicable.

[1] For the purpose of this report the April 5, 1994 version of 10 C.F.R. § 830.120 was used and the section numbering in the report refers to that version. The Quality Assurance criteria promulgated on January 10, 2001 are unchanged from the previous version.

Such requirements notwithstanding, there is evidence that DOE's QA program is falling well short of its objectives of ensuring high quality in the design, procurement, and fabrication of products that must serve safety functions. Such failure has resulted in defective equipment. By letter dated December 1, 1999, the Defense Nuclear Facilities Safety Board (Board) cited specific instances of inadequate QC reported by the Board's staff during the past 2 years. These observations confirmed more general quality issues identified by DOE's Office of Independent Oversight (EH-2) in a special topical report on QA, a part of the 1998 special assessment report entitled *DOE Safety Performance Within Key Topical Areas*. DOE has failed to date to address this issue in any comprehensive way. A DOE Quality Assurance Working Group (QAWG) has been tasked to develop a path forward. In a briefing provided to the Board by the QAWG on June 19, 2000, in response to the Board's December 1999 letter, the Board was advised that root causes for the decline in adequate implementation of DOE's QA program have been:

- Reductions in budget/staffing levels, resulting in fewer procurement reviews and inspections (i.e., shortchanging the process),

- Lack of or inadequate line attention to oversight by DOE and its contractors (i.e., failing to satisfy responsibilities), and

- Improper application of the selected codes and standards for QA (i.e., performing faulty engineering).

The deficiencies of DOE's QA program merit a much more in-depth assessment than these simple conclusions suggest. Such a review needs to encompass (1) the historical and current management philosophy on which DOE's QA program is based; (2) the guidance DOE has issued to explain its expectations to contractors; (3) the contractors' manuals of practice that are responsive to DOE requirements or guidance; and (4) the implementation of those practices by the contractors as they design, procure/fabricate, inspect/accept, install, and operate/maintain equipment serving important safety functions.

At the Board's continued urging, the Program Secretarial Officers of both Defense Programs and Environmental Management have initiated self-assessment actions. Progress to date has not been impressive.

In the sections that follow, the various aspects of DOE's QA program are addressed. Concluding observations are then provided that might well be considered by DOE in further performing its self-assessments and structuring improvement programs.

2. HISTORICAL QUALITY ASSURANCE PROGRAMS

2.1 QUALITY ASSURANCE: NUCLEAR INDUSTRY

QA for the nuclear industry evolved from QC practices that came to the forefront with mass production stimulated by World Wars I and II. Those quality requirements became embedded in Military Specifications (Mil Specs) and industrial codes and standards. A fundamental aspect of design engineering entailed the specification of applicable codes and standards to ensure the quality judged necessary for the applications. QC was exercised through use of statistical process control techniques. However, in the nuclear applications the statistical component was essentially converted into a requirement for one hundred percent conformance. Any known non-conformance required correction.

As the naval reactor and commercial nuclear power programs grew during the 1950–1970 period, the engineering practice of QA emerged. QA programs took QC to a higher level by adding another audit, independent of the production line, to further ensure that products and services met specifications.

A chronology of the development of QA standards is provided in Appendix A. Key milestones are as follows. In 1967, QA requirements were captured in Appendix IX of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section III. In 1968, ASME established an ad hoc planning committee, N.45, to develop a QA code covering critical reactor components during plant construction. In 1969, the Atomic Energy Commission's (AEC's) Division of Reactor Development and Technology, building upon practices employed by the naval reactor program, together with quality standards of the National Aeronautics and Space Administration (NASA) and the Department of Defense (DoD), issued RTD Std. F2-2T. In 1970, AEC's regulatory unit issued 10 C.F.R. Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants*. Although 10 C.F.R. Part 50, Appendix B, has been amended a number of times during the past 30 years, the basic set of elements required of QA programs by the Nuclear Regulatory Commission (NRC) has remained consistent. In 1975, the American National Standards Institute (ANSI) assigned overall responsibility for coordination among technical societies and development and maintenance of standards for Nuclear Quality Assurance (NQA) to ASME. The ASME committee on QA prepared standards NQA-1 in 1979 and NQA-2 in 1983. NQA-1 was revised and republished in 1983, 1986, 1989, 1994, and 1997. NQA-2 targeted a number of specialized systems not explicitly treated in NQA-1. The 1983 version was revised and reissued in 1986 and 1989. The 1997 version of NQA-1 is now structured in three parts: Part I (former NQA-1), Part II (former NQA-2), and Part III (nonmandatory guidance).[2]

[2] It may be noted that Dr. John Stevenson reported to the Board in 1992 that there were no formal QA programs for construction of commercial nuclear facilities prior to 1969, and that approximately 40 percent of the existing operating (nuclear) utilities had been built before 1974 and were not subject to any formal QA requirements. The one exception was the construction of pressure vessels to the ASME Boiler and Pressure Vessel Code.

NQA-1 is essentially the nuclear industry's response to the NRC's 10 C.F.R. Part 50, Appendix B. NQA-1 builds on the NRC's 18 basic criteria, and captures consensus on "how-to" practices for satisfying NRC requirements. Particularly noteworthy is the more explicit treatment of organizational structure and responsibilities set forth in Section 201:

> The organizational structure and responsibility assignments shall be such that:
>
> (a) Senior management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result;
>
> (b) quality is achieved and maintained by those assigned responsibility for performing work; and
>
> (c) quality is verified by those not directly responsible for performing the work.

Note that failure to recognize and perform these distinct functions in a complementary way is a root cause of problems experienced in achieving quality objectives. This point will be discussed later.

For a number of years, the Southwest Research Institute published *A Comparison of 10 C.F.R. Part 50, Appendix B and ASME NQA-1*. The last version is dated April 1991. The Board's staff has been advised there are no plans for an update. A comparison of QA standards provided in Appendix B of the present report includes the NRC's 10 C.F.R. Part 50, Appendix B; ASME's NQA-1 (Parts I and II); DOE's 10 C.F.R. § 830.120; and the International Standards Organization's (ISO) 9001. One can note the differences between DOE's criteria and those of NQA-1.

As the commercial nuclear power industry matured, its major activities shifted from design, fabrication, and installation of vital systems to operation and maintenance. In response, the American Nuclear Society (ANS) issued an American National Standard, ANS 3.2, *Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants*, dated December 1994.

While systems, structures, and components serving vital safety functions have traditionally been the focus of quality attention, the science and engineering adjuncts that are the underpinnings of their design also fall within the nuclear safety QA domain. This point is illustrated in Figure 1. The importance of special attention to computer software to ensure confidence in the reliability of results derived from its use was recognized by the inclusion of Part 900, "Software Design Control Requirements," in the1997 version of NQA-1.

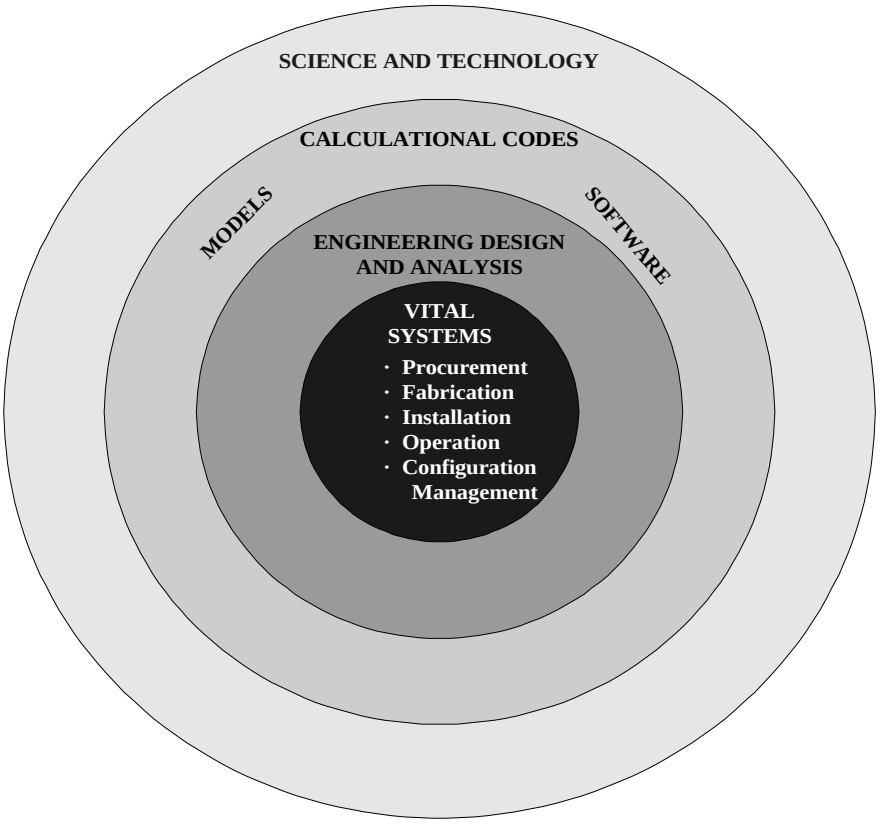

Figure 1. Nuclear Quality Assurance

2.2 QUALITY ASSURANCE: NUCLEAR REGULATORY COMMISSION

For licenced nuclear facilities, the NRC's requirements for QA are set forth in 10 C.F.R. Part 50, Appendix B. As noted earlier, this is a rule that was first established in 1970 by regulatory staff of the AEC, the predecessor of the NRC. The introduction to 10 C.F.R. Part 50, Appendix B, makes quite clear the intended target for this special quality attention and the relationship between QC and QA. In any discussion of QA, it is important to understand and appreciate the original thrust and intent of QA, as explained in the introduction to 10 C.F.R. Part 50, Appendix B. Passages that are especially cogent and particularly pertinent to this paper are as follows:

> Nuclear power plants and fuel reprocessing plants include structures, systems and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix

establishes QA requirements for the design, construction, and operation of those structures, systems and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

It is interesting to note that the NRC in 1985 endorsed the 1983 version of NQA-1. This version was developed from fragmented ANSI, DoD and NASA quality assurance requirements. Reportedly, only two NRC licensees adopted NQA-1. NRC never endorsed later revisions of NQA-1 that changed some of the earlier "requirements" to "suggestions."

2.3 QUALITY ASSURANCE: DEPARTMENT OF ENERGY

As described in Section 2.1, DOE's formal program of QA emerged largely from the naval reactor and NASA programs and the AEC's early efforts to ensure the safety commercial applications of nuclear power in the 1965–1975 era. Although these AEC efforts provided the underpinnings of practices adopted eventually by the NRC (in 10 C.F.R. Part 50, Appendix B) and the commercial nuclear industry (in NQA-1 and NQA-2), such practices were never applied in the construction of most of the existing DOE nuclear complex. A chronology of the development and application of QA practices is summarized in Appendix A.

Relative to DOE's current QA program, certain aspects relating to its evolution during the 1980–2000 time period are particularly noteworthy. These are as follows:

- The precursor of DOE's current QA requirements was established in 1981 as DOE Order 5700.6. These requirements to a large extent mirrored the 18 basic criteria of ASME NQA-1 (1979), the then existing industry standard.

- DOE Order 5700.6.A (1982) and 5700.6.B (1986) addressed DOE's organizational changes in responsibility for QA and QA training and qualification.

- DOE Order 5700.6.C (1991) was a major restructuring. The 18 criteria of NQA-1 were pared down to 10. This restructuring was directed, reportedly (Duncan and Van Matre, 1990), at effecting a radical departure from the long-standing focus on quality

of systems and components important to ensuring public nuclear safety and the documentation of adherence to processes and procedures to:

- Integrate quality requirements into all work (i.e., all mission tasks).
- Emphasize achievement of quality attributes (versus documentation of processes).
- Reaffirm the role of line management rather than a QA auditing organization as having primary responsibility for quality objectives.

Order 5700.6.C was, in effect, the beginning of a shift by DOE to the concept of Total Quality Management (TQM) (Duncan and Van Matre, 1990; Bank, 1992). (See Section 2.5.)

The requirements and the TQM philosophical approach embedded in DOE Order 5700.6.C were subsequently made applicable by 10 C.F.R. § 830.120 (1994) for contractors subject to Price-Anderson indemnification provisions and by DOE Order 414.1A (September 29, 1999). DOE Guide 414.1-2 (June 17, 1999) was issued to provide guidance on DOE's expectations for QA programs to satisfy the requirements. In the reissue of Section 830.120 (November 2000) as a component of a revised nuclear safety rule 10 C.F.R. § 830, remnants of the TQM approach were retained.

2.4 QUALITY ASSURANCE: INTERNATIONAL STANDARDS ORGANIZATION'S ISO 9000

Like its national counterpart (NQA-1) the international standard ISO 9001 (1994) specifies quality system requirements for use when a supplier's capability to design and supply conforming parts needs to be demonstrated. ISO 9000-3 is a companion guideline for application to the development, supply, and maintenance of software. These standards provide for a certification process for those who wish to be recognized as compliant providers of products and services.

2.5 NUCLEAR QUALITY ASSURANCE VERSUS TOTAL QUALITY MANAGEMENT

NQA and the more encompassing TQM concepts that came into vogue in the United States during the 1980s have common roots (U.S. Department of Energy, 1994). These roots go back to practices that emerged in the 1920s when Walter Shewhart of Bell Laboratories developed a statistical control process for monitoring consistency and diagnosing problems in work processes. Shewhart also created the Plan-Do-Check-Act cycle, a systematic, scientific method of improving work processes. (The five functions of Integrated Safety Management [ISM], DOE Policy 450.4, are a version of this basic model).

During World War II, the War Department hired W. Edwards Deming, a physicist and Census Bureau researcher, to teach statistical process control to the defense industry. Deming took his teachings to Japan at the invitation of the United States occupation forces following World War II to help that nation with its postwar census and to teach business leaders about statistical process control and quality. Deming's teachings, along with those of two other Americans, Joseph Juran and Armand Feigenbaum, who also worked with the Japanese, evolved into the concept of TQM. The ultimate goal of course, was achieving greater competitiveness for Japanese products. That goal was to be achieved in part through quality workmanship, but Deming et al. advocated other measures as well.

These early advocates of TQM took the more traditional product-focused approach (e.g., NQA) to a higher level by stressing that achievement of competitiveness required virtually constant management scrutiny of organization-wide activities with an eye to constant improvements. This scrutiny included not only the quality of products and services, using "customer satisfaction" as a gauge, but also products and services developed internally by one organizational unit in support of the work of another, such as strategic plans, budgets, safety analyses, contracts, procurements, and the myriad interoffice exchanges of work products. TQM, in effect, is a management concept that involves everyone in an organization in constructively self-critiquing the work process in which they are engaged, and doing so under a management regime that fosters and reacts to such critiquing. TQM is just one of a number of methods of management used by corporate entities to effect improvements in the products of their organizations. Product improvements to enhance competitiveness and profits and sustain corporate viability are the principal motivation. Other similar quality management systems or philosophical approaches (Center for Chemical Process Safety, 1996) include:

- The ISO 9000 series, *Quality Management and Quality System Elements—Guidelines*.
- The ISO 14000 Series, *Environmental Management*.
- The Malcom Baldridge National Quality Award.
- The European Quality Award.
- The Deming Quality System.

A brief summary of these management systems as published by the Center for Chemical Process Safety (1996) is provided with the Center's permission as Appendix C to this report.

Of interest to note about these TQM systems is that much emphasis is placed on management processes and total employee involvement, but the "quality" of a product is never really defined. Apparently one will know quality when one experiences it or sees evidence of it through customer satisfaction.

More importantly for government agencies such as DOE, these TQM concepts require adaptation to the agency's diverse functions and organizational entities. Furthermore, programs directed at improved services require constancy and consistency. This can be a formidable task—one that becomes more daunting in government, where top administrators change frequently, and no central force keeps a constant focus and ensures adequate resource loading to achieve the goals sought.

In 1993, with the endorsement of the National Performance Review and the leadership of Secretary of Energy Hazel R. O'Leary, DOE embraced use of the TQM concept. In June 1994, implementation guidelines were issued, and an Energy Quality Council was established. DOE embarked on an effort to achieve high quality in the performance of all its diverse missions. The movement to TQM as the core management theme for DOE lost its momentum with the departure of Secretary O'Leary.

Unfortunately, the NQA program that historically had been focused on ensuring the reliability and dependability of systems serving vital nuclear safety functions became muddied in this shift by senior DOE management toward TQM. This is evident in the language of 10 C.F.R. § 830.120 (2000), and more so in DOE Guides 414.1-1 (1996) and 414.1-2 (1999). For example, the following are excerpts from DOE Guide 414.1-2:

> The quality attained in a product or service is described by the extent to which that product or service satisfies the requirements, needs, and expectations of the customer. (As used in this Guide, the term "customer" includes all entities that supply to or receive products and services from the organization, including DOE, regulators, stakeholders, public, contractors, suppliers and employees). The attainment of quality is the responsibility of each member of an organization.
>
> . . . The concept of developing a management system to simultaneously satisfy the requirements of a nuclear safety rule, those of an integrated management systems policy and regulation and an overall quality management system for items and services produced by an organization may at first appear inconsistent or unworkable. Experience has shown, however, that designing a system to a minimum performance level will inevitably result in less than minimum results.
>
> The QA Order and rule require that an organization develop, document and maintain an effective QA program, hereafter referred to as a quality management system. The goal of the quality management system is delivery of safe, reliable products and services that meet or exceed the customer's requirements, needs and expectations. . . . The quality management system is intended to support and function with the Department's ISMS [Integrated Safety Management System].
>
> The quality management system should focus on properly and safely accomplishing the mission, as outlined, for example, in the organization's strategic plan. Therefore, every component and employee of the organization is included within the quality management system's scope, which addresses the organizational structure, functional responsibilities, levels of authority, and interfaces.

> . . . [E]very individual in the organization is responsible for achieving quality in his or her activities. Senior management should require and cultivate the achievement and improvement of quality at all levels of the organization. . . .

This guidance, notwithstanding, this attempt to meld the TQM concept with NQA practices and other DOE safety policies and requirements is problematic. (See Section 3.2).

3. OBSERVATIONS

3.1 STATUS OF QUALITY ASSURANCE IMPLEMENTATION AT DEPARTMENT OF ENERGY FACILITIES

3.1.1 Historical Context

Virtually all DOE nuclear facilities built prior to 1980 were constructed without formal QA programs (Stevenson, 1992). This historical fact notwithstanding, one should not conclude that DOE nuclear facilities were poorly built. Most were designed, constructed, and operated originally by those experienced in safe practices as applied at the time by the chemical industry. The long, useful life of DOE facilities, most constructed in the 1940–1960 era, says much for the quality of their design and construction. The history of operations in the post-1980 period, however, does not attest to the same attention to quality maintenance and configuration management of vital systems.

In 1981, in the aftermath of the Three Mile Island accident, a special task force performed a comprehensive survey of the safety management of DOE's reactors (U.S. Department of Energy, 1981). The review included the application of QA concepts. The task force's report cited substantial deficiencies in programs intended to ensure quality in systems serving safety functions. These citations led to the issuance of DOE Order 5700.6 as recounted in Section 2.1. More recently, in 1998, DOE's independent safety assessment group (EH-2) identified general QA issues throughout the DOE nuclear complex.

During the past 3 years, the Board's site representatives have observed and reported numerous cases in which necessary QA measures were not taken. The Board sent nine letters to senior DOE management regarding QA during this time. A summary list of these reports and letters is included as Appendix D. In January 2000, the Board issued DNFSB/TECH-25, *Quality Assurance for Safety-Related Software at Department of Energy Defense Nuclear Facilities* (Defense Nuclear Facilities Safety Board, 2000). In this technical report, the Board identified root causes of poor software QA.

The result to date of these interchanges has been to stimulate DOE to undertake a two-part QA reassessment program: one part directed toward software QA programs and activities and the other part toward hardware QA programs and activities (NQA-1). These assessments have been proceeding at a tortoise-like pace as separate initiatives along programmatic lines—Defense Programs, Environmental Management, and the Chief Information Officer. In the meantime, DOE issued QA Rule 10 C.F.R. § 830.120 in December 2000, which includes provisions that can be interpreted as enlarging the scope of DOE's QA program subject to enforcement provisions of the Price-Anderson AmendmentsAct.

3.1.2 Contractors' Quality Assurance Program Plans and Manuals of Practice

All of DOE's major maintenance and operating contractors are required to have QA programs consistent with the requirements of DOE's Rule 10 C.F.R. § 830.120. Such requirements also flow down to subcontractors. The Rule requires that the contractors' QA program descriptions be reviewed and approved by DOE.

The Board's staff conducted a brief survey of contractors' QA program descriptions and manuals of practice at a number of DOE sites (Rocky Flats Environmental Technology Site, Savannah River Site, Hanford Site, Los Alamos National Laboratory, Lawrence Livermore National Laboratory, Idaho National Engineering and Environmental Laboratory). Summary descriptions of these programs are included as Appendix E. One can note several important points from these summaries:

- The contractors' QA programs are based largely upon industry standards, NQA-1, 2, 3 and ISO 9000; that is, they are nuclear safety in their orientation, not TQM.

- Requirements have been amplified and proceduralized in a substantial number of manuals of practice.

Hence, one can reasonably conclude that whatever deficiencies exist in DOE's QA program, they are not due to a lack of contractors' program descriptions or procedural guidance. The problem is one of a failure to implement known good practices.

DOE's contractors are frequently interested in offering quality management programs for which they have been "certified," such as the Voluntary Protection Program, ISO 9001, and ISO 14001. Vendor certifications and approvals typically fall into three categories (Carr, 1993), based on audits and vendor documentation:

- Certified Vendor—Quality system reviewed and accepted; proven quality, delivery, and value demonstrated; incoming products not inspected when delivered.

- Approved Vendor—Quality system reviewed and found acceptable; quality, delivery, and value subject to review; statistical sampling, at least, for receipt inspection.

- Non-Rated Vendor—Quality system unknown or under review; quality, delivery, and value subject to review; receipt inspection required.

Prequalifying vendors through certification or similar processes is a good practice but is not sufficient unto itself. Quality requirements need to be clearly defined for all services and products important to safety, and products received must be subject to sufficient incoming inspection so as to make certain that they conform to specifications.

3.2 DEPARTMENT OF ENERGY'S CURRENT QUALITY ASSURANCE REQUIREMENTS

DOE's QA rule appears to have established TQM as its fundamental requirement. NQA as traditionally practiced according to industry standards is acceptable as a subsystem. This is inferred from Section 4.1.1 of DOE Guide 414.1-2 (1999), wherein it is stated:

> The rule and Order requirements are stated as performance expectations and do not specify methods for achieving the desired performance. Consequently, organizations

should identify, document, and use appropriate standards to develop and implement the management system. . . . Organizations with multiple customers must often develop their management system using several standards. . . . e.g.: a single facility may adopt ISO 9001 for corporate reasons, ASME NQA-1 from an EPA/NRC [and DOE] regulation and "QC-1" for nuclear weapons activities. . . .

DOE's current policies, rules, orders, and guides relative to QA contain such an assortment of management philosophies and guidance as to confuse DOE's expectations for its own staff and its contractors. The traditional focus on high-quality products important to safe operations with nuclear material (NQA) appears to have become subsumed under a more enveloping quality management concept (TQM). As summarized in Section 2.5, TQM is a management concept that involves everyone in an organization constructively critiquing the work processes in which they are engaged, with the objectives of productivity, efficiency, and greater customer satisfaction. The relationship between TQM and NQA is illustrated by Figure 2.

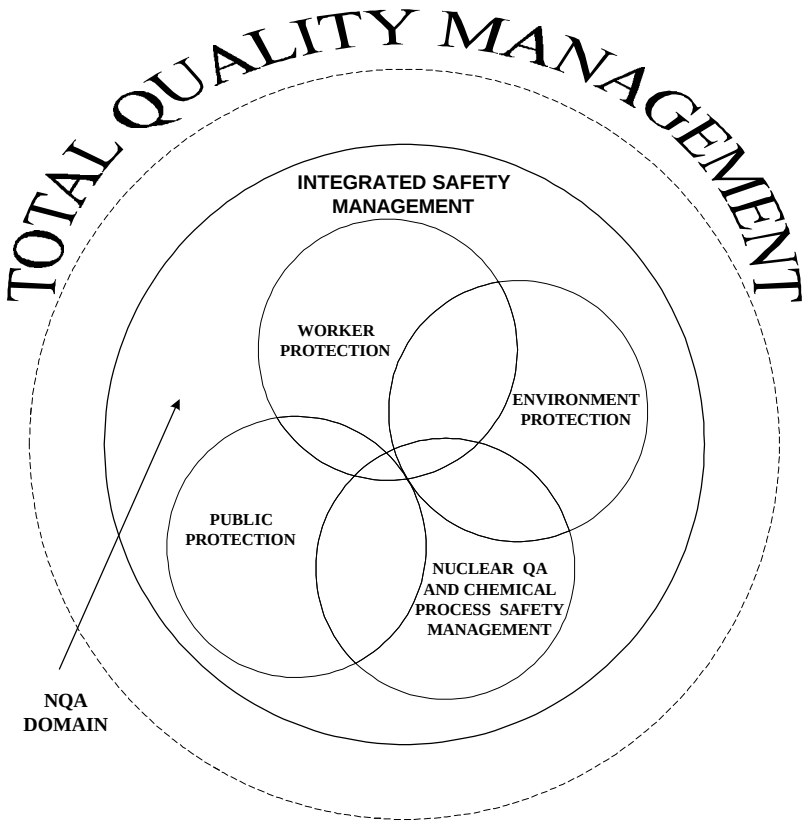

Figure 2. Relationship Between Total Quality Management and Nuclear Quality Assurance

This attempt by DOE to meld TQM and NQA concepts into one QA program may, on the surface, appear meritorious to those striving for excellence in all products and services provided by DOE. However, given DOE's organizational structure, with its diversity of programs and its frequent changes in both top-level administration and major operating contractors, the chances for successful integration are quite small, and the resources required to establish and implement TQM complex-wide quite large. A program to ensure high quality in the services and engineered systems required to ensure safety should not be made dependent upon the adaptation and successful implementation of TQM concepts for the overall operation of DOE.

3.3 TOTAL QUALITY MANAGEMENT VERSUS PRICE-ANDERSON ACT

The major driver for the issuance of 10 C.F.R. § 830, including 10 C.F.R. § 830.120 on QA, was to enlarge the set of DOE nuclear safety requirements subject to enforcement provisions under the Price-Anderson Amendments Act (1988). A QA program structured for TQM will very likely complicate the identification and quality control of services and products provided by DOE contractors that are subject to those provisions. DOE's NQA program is already beset with implementation problems and does not need to be further complicated. At a DOE workshop held November 28–30, 2000, in Las Vegas, Nevada, the head of DOE's Office of Enforcement and Investigation (EH-10) advised that he anticipated no change in enforcement action under the Price-Anderson Amendments Act with 10 C.F.R. § 830. This expressed intent notwithstanding, the guidance currently in DOE Guide 414.1-2 is oriented much more toward the use of TQM than NQA for quality management. One can conclude that there is a disconnect between those who have fashioned the new rule and associated guides and those who are charged to implement and/or enforce them. This disconnect needs to be addressed.

3.4 QUALITY CONTROL VERSUS QUALITY ASSURANCE

Effective NQA programs are essentially QC programs subject to independent audits of specified quality requirements. This relationship is illustrated by Figure 3 using the eighteen criteria of NQA-1.

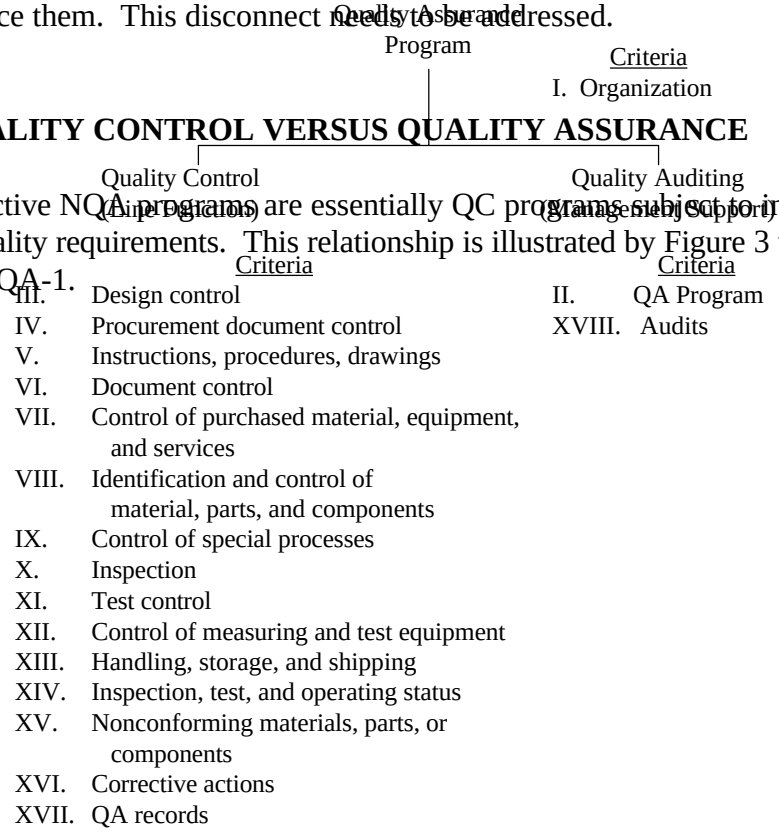

Figure 3. Criteria for Nuclear Quality Assurance

The ISM principle that line management has primary responsibility for safety is particularly pertinent to ensuring the requisite reliability, operability, and safety of vital safety systems and related services. QA organizations should not be looked to for the specification of requirements. The area requiring principal attention by DOE relative to its contractors' NQA programs is the emphasis placed by line managers on quality requirements in the design, procurement, fabrication, construction, and operation of vital safety systems. QC inspectors and QA auditors make doubly sure that products are made and services are performed as planned, but specifying the way things should be made or done is not within their purview.

The major problem as evidenced by quality problems cited in Appendix D, results largely from failure on the part of line managers to insure that: (1) appropriate quality-related requirements are specified for products for which they are responsible, and (2) satisfaction of those requirements is evidenced in the products delivered for use. High quality products require that line management be closely involved throughout product design and development, procurement, fabrication, construction, and operation. These functions are commonly performed by different organizational units. Control and oversight by line management of these interfaces is very important if quality requirements defined in design are to be achieved in the product. Quality Assurance organizations can and do provide management support in setting up QA programs and assessing the effectiveness of them but line managers must retain principal responsibility for product quality.

3.5 INTEGRATED SAFETY MANAGEMENT VERSUS DOE QUALITY ASSURANCE (RULE 10 C.F.R. § 830.120)

DOE Rule 10 C.F.R. § 830.120 and DOE Order 414.1-A require that contractors "integrate the quality assurance criteria with the Safety Management System (SMS), or describe how the quality assurance criteria apply to the Safety Management System." According to the rule's preamble, this requirement is being added because:

> The Department expects that quality assurance criteria and practices will be embedded in all work processes, not just those that relate to nuclear safety. Therefore, the actions to implement the quality assurance criteria should be integrated with and consistent with the commitments in the SMS. This helps

ensure that quality assurance criteria and practices will apply to all work processes that are implemented for safety management.

Two options are provided in the rule for meeting this requirement. First, the contractor can maintain separate ISM descriptions and Quality Assurance Program (QAP) documents, but must describe in the latter documents how the QA criteria are applied to the ISM program. Second, the contractor may incorporate the QAP documents into the ISM description. This approach requires that the ISM description specify how the QA criteria are to be met. (Note that the second option creates problems in that the contractor is held to the approved QAP documents for nuclear safety enforcement actions.)

According to EH representatives at a workshop on ISM held at the Hanford Site:

[T]his requirement is intended to show how the quality management systems are integrated into the ISM system to form one management system. For example, *QA Criteria 1—Management Program (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work,* is clearly addressed in the ISM system description making it unnecessary to also address it in the QAP. This is similar for other QA Management and Assessment Criteria (1, 2, 3, 4, 9 and 10.) However, there are other criteria that are not addressed explicitly in the ISM system. For example, Criteria 5—Work Processes, 6—Design, 7—Procurement and 8–Inspection and Acceptance Testing, are separate quality processes that must be called upon when planning and conducting work under the ISM system to ensure a quality output or product.

While this requirement has been inserted into 10 C.F.R. § 830.120 and DOE Order 414.1-A, DOE has not yet provided sufficient guidance on what is expected of its contractors. Most important, the relationship encouraged by DOE relative to NQA, QA under 10 C.F.R. § 830.120, and ISM needs to be established. The author's view of this relationship is illustrated by Figures 1 and 4, and summarized below.

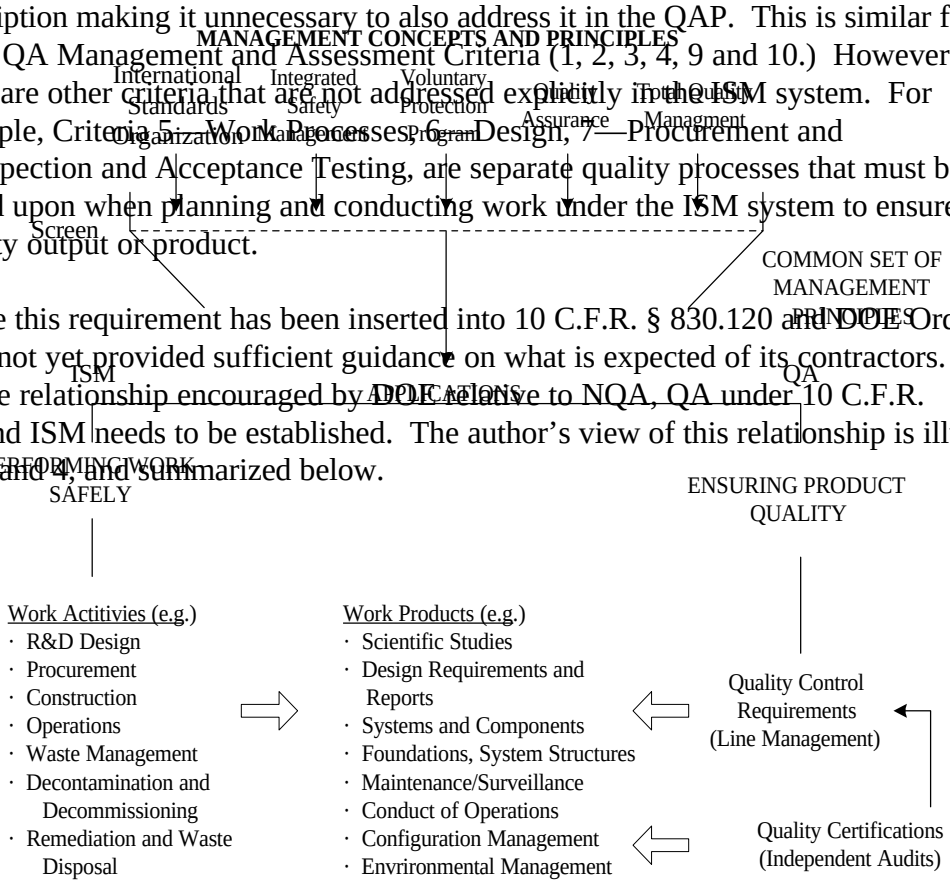

Figure 4. NQA Relative to ISM

ISM and NQA need to be treated as complementary functions and managed at the top by the same organizational entities. ISM is intended to instill a consistent way of planning and performing hazardous work. QA programs are intended to systematically define quality requirements for all activities involved in this work. Basic steps in this planning and performing exercise are defined as five core functions of ISM:

1. Definition of the Work
2. Analysis of the Hazards
3. Identification of Safety Requirements
4. Performance of the Work (Satisfy Safety Requirements)
5. Feedback and Improvement

The results of exercising these functions are a large variety of products (see Figure 4).

Because of its safety significance (need to protect the public, workers, and the environment), all work done to satisfy these five core ISM functions must be performed with such rigor as to provide high confidence in the reliability and dependability of the resulting products, whether they be equipment (e.g., systems and components or analyses and reports) or services (e.g., nuclear facility operations, research and development, decontamination and decommissioning). (See Figure 1.)

NQA programs are targeted at ensuring the reliability and dependability of products and services important to safety. Such programs are made up of two basic parts: (1) establishing quality requirements and exercising QC, and (2) auditing QC measures for added assurance. Quality requirements are in turn graded to reflect the safety significance of the products produced or services provided.

ISM, per the Department of Energy Acquisition Regulations and QA requirements per 10 C.F.R. § 830.120, include management principles/criteria that are essentially identical. Similar principles have been defined for other safety management programs, such as the Voluntary

Protection Program and Environmental Management System (ISO 14001). In the author's view, it is showing how these various safety-related programs are interlinked and managed as a whole by contractor management that is encouraged by Requirement 1a.(3)(c) of 10 C.F.R. § 830.120 (see Figure 4).

The most important aspects of NQA that contractors need to address are (1) how they plan to satisfy their responsibilities to ensure that the requisite quality-related specifications are defined for their safety-related products and services, and (2) how they will ensure that such quality specifications are subsequently satisfied in the products and services they provide to the government. Prequalifying vendors through certification or similar processes is a good practice but is not sufficient unto itself. Quality requirements need to be clearly defined for all services and products important to safety, and products received must be subject to sufficient incoming inspection so as to make certain that they conform to specifications.

DOE has established ISM as its corporate model for doing work safely and providing feedback to effect safety improvements. The functions and principles embodied in ISM have much in common with TQM concepts. These include:

- Senior-level management commitment.
- Promotion of safety as an organizational value.
- Encouragement of worker involvement at all levels.
- Promotion of lessons learned and teamwork for continuous improvement.
- An institutionalized system framework.

Before DOE undertakes to expand its quality horizons to encompass all work products and services, it would do well to fully implement those quality programs required to ensure the safety of its hazardous operations.

APPENDIX A

CHRONOLOGY DEVELOPMENT AND APPLICATION OF QUALITY ASSURANCE PRACTICES

Date	Org.	Number	Subject
1954	AEC	QC-1	QC for AEC weapons programs.
1958/ 1963	DoD	MIL-Q-9858A	Quality specifications (procurement, manufacturing, fabrication, assembly, construction, and installation).
1962/ 1969	NASA	NPC 250-1	Quality standard (design and development engineering).
1962/ 1969	NASA	5300.4(1B)	Quality standard (manufacturing, fabrication, assembly, construction, and installation).
1964	AEC	QRC-82	QC for AEC naval reactors program.
1965	AEC	10 C.F.R. Part 50 Criterion 1	Design/QA criteria for licensed nuclear power plants.
1967	ASME	Appendix IX	Boiler and Pressure Vessel Code Section III (QA requirements for nuclear vessels, components, piping, pumps, and valves).
1968	ASME	N.45	Established an ad hoc planning committee for developing a QA code covering critical reactor components during plant construction.
1968	AEC Division of Reactor Licensing	-	Issued criteria and requirements for instrumentation and controls for nuclear power plants.
1968	AEC Division of Reactor Licensing	-	Initiated a program with Virginia Electric Power Company to monitor a QA program during construction of the Surry Plant. Resulting information and requirements are to be used in codes and standards.
1969	AEC	RDT Standard F2-2T	Quality assurance requirements for life cycle phases. Based on NASA and DoD quality standards and specifications referenced earlier.
1970	AEC	10 C.F.R. Part 50 Appendix B	*Quality Assurance Criteria for Nuclear Power Plants.*
1971	AEC	10 C.F.R. Part 50 Appendix B	*Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants (amendment).*
1971	ASME	N45.2	*Quality Assurance Program Requirements.*

Date	Org.	Number	Subject
1971	ASME	N45.2	*Quality Assurance Program Requirements for Nuclear Power Plants.*
1971	ASME	ANSI/ASME N45.2	National consensus QA program standard.
1972	ASTM	N101.4	*Quality Assurance for Protective Coatings Applied to Nuclear Facilities.*
1973	AEC	AEC 0820	AEC QA Policy.
1974	ASME	N45.2.5	*Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations During the Construction Phase of Nuclear Power Plants.*
1974	ASME	N45.2.11	*Quality Assurance Requirements for the Design for Nuclear Power Plants.*
1975	ASME	N45.2.8	*Supplementary Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for the Construction Phase of Nuclear Power Plants.*
1976	ASME	N45.2.13	*Quality Assurance Requirements for Control of Procurement Items and Services for Nuclear Power Plants.*
1976	ANS	N18.7	*Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants.*
1976	ANS	3.2	*Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants.*
1977	ASME	N45.2	*Quality Assurance Program Requirements for Nuclear Power Plants.*
1977	AMSE	N45.2.12	*Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants.*
1977	ERDA	ERDA 0820	Revised AEC QA policy.
1979	ASME	ANSI/ASME NQA-1	Consolidated N45.2 QA program standard.
1981	DOE	DOE 5700.6 and 6.A	DOE QA policy.
1983	ASME	NQA-1a Addenda	*Quality Assurance Program Requirements for Nuclear Power Plants.*

Date	Org.	Number	Subject
1983	ASME	NQA-1	*Quality Assurance Program Requirements for Nuclear Power Plants.*
1983	ASME	ANSI/ASME NQA-2	Consolidated N45.2 QA methods.
1986	ASME	NQA-1	QA program requirements for nuclear activities.
1986	DOE	DOE 5700.6B	Revised DOE QA policy.
1987	ISO	ISO 9000	*Quality Management System.*
1989	ASME	NQA-1	*Quality Assurance Program Requirements for Nuclear Facilities.*
1989	ASME	NQA-2	*Quality Assurance Requirements for Nuclear Facility Applications.*
1990	ASME	ANSI/ASME NQA-3	QA data standard.
1991	DOE	QC-2	DOE weapons QA program for Research and Development
1991	DOE	10 C.F.R. § 830.35	Proposed DOE QA Rule.
1991	DOE	DOE 5700.6C	Revised DOE QA Order.
1994	ISO	ISO 9001	*Quality Systems, Model for QA in Design, Development, Production, Installation, and Servicing.*
1994	DOE	10 C.F.R. § 830.120	Quality assurance requirements.
1994	ASME	NQA-1, 2, 3	*Quality Assurance Requirements for Nuclear Facility Applications.*
1994	ANS	ANSI/ANS Standard 3.2	*Administrative Controls and QA for the Operational Phase of Nuclear Power Plants.*
1994	ASME	NQA-1	Revision and consolidation of NQA-1-1989 and NQA-2-1989 editions.
1996	DOE	DOE Guide 414.1-1	*Independent and Management Assessment Requirements of 10 C.F.R. § 830.120 and DOE 5700.6C Quality Assurance*
1997	ASME	NQA-1	Update/Revision of 1994 edition, Part I—Basic Requirements, Part II—*QA Requirements for Nuclear Facility Applications.*
1998	ASCE	JCEM, Vol 124, No 3	Factors that Affect Process Quality in the Life Cycle of Building Projects

Date	Org.	Number	Subject
1999	DOE	DOE Order 414.1A	*Quality assurance*.
1999	DOE	DOE Guide 414.1-2	*QA Management System Guide.*
2000	DOE	10 C.F.R. § 830.120	*Nuclear Safety Management, Quality Assurance Requirements.*

APPENDIX B

COMPARISON OF NRC'S 10 C.F.R. PART 50 APPENDIX B, ASME'S NQA (PARTS I AND II), DOE'S 10 C.F.R. § 830.120, AND ISO 9001

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
Introduction: Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the Quality Assurance Program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Nuclear power plants and fuel reprocessing plants (Amended 36 FR 18301) include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes Quality Assurance requirements for design, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.	**Introduction:** 1. Purpose. This Part (Part I) sets forth requirements for the establishment and execution of Quality Assurance Programs for the siting, design, construction, operation, and decommissioning of nuclear facilities. Nonmandatory guidance is provided in the Appendices in Part III. 2. Applicability. The requirements of this Part (Part I) apply to activities which could affect the quality of structures, systems, and components of nuclear facilities. Nuclear facilities include facilities for power generation, spent fuel storage, waste storage, fuel reprocessing, and plutonium processing and fuel fabrication. These activities include the following: (a) the performing functions of attaining quality objectives; (b) the functions of assuring that an appropriate Quality Assurance Program is established; and (c) the function of verifying that activities affecting quality have been correctly performed. Activities affecting quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning.	**Quality Assurance Requirements:** (a) General Rule. (1) A contractor responsible for a DOE nuclear facility shall: (i) Conduct its work in accordance with the criteria of paragraph (c) of this section; (ii) Develop and submit for approval by DOE a Quality Assurance Program (QAP) for the work; and (iii) Implement the QAP, as approved and modified by DOE.	**1 Scope** This International Standard specifies quality system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated. The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design to servicing. This International Standard is applicable in situations when (a) design is required and the product requirements are stated principally in performance terms, or they need to be established, and (b) confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in design, development, production, installation and servicing.

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
Introduction (continued): As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those Quality Assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.	**Introduction (continued):** The application of this Part (Part I) or portions thereof, shall be specified in written contracts, policies, procedures, or instructions. 3. Responsibility. The organization invoking this Part (Part I) shall be responsible for specifying which Basic Requirements and Supplements, or portions thereof, apply, and appropriately relating them to specific items and services. The organization upon which this Part (Part I), or portions thereof, is invoked shall be responsible for complying with the specified requirements.	**Quality Assurance Requirements (completed)**	**1 Scope (completed)**

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
I. Organization: The applicant shall be responsible for the establishment and execution of the Quality Assurance Program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the Quality Assurance Program, or any part thereof, but shall retain responsibility therefor. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the Quality Assurance functions. The Quality Assurance functions are those of (a) assuring that an appropriate Quality Assurance Program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing Quality Assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Such persons and organizations performing Quality Assurance functions shall report to a management level such that this required authority and organizational freedom, including	**II. Basic and Supplementary Requirements 1 - Organization:** The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. Persons or organizations responsible for assuring that an appropriate Quality Assurance Program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to: (a) identify quality problems; (b) initiate, recommend, or provide solutions to quality problems through designated channels; (c) verify implementation of solutions; and (d) assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.	**(c) Quality Assurance Criteria** (1) *Management* (i) *Program*. A written QAP shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe management processes, including planning, scheduling, and resource considerations. (ii) *Personnel Training and Qualification*. Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained. (iii) *Quality Improvement*. Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.	**4.1.2 Organization** **4.1.2.1 Responsibility and authority** The responsibility, authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to: a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system; b) identify and record any problems relating to the product, process and quality system; c) initiate, recommend or provide solutions through designated channels; d) verify the implementation of solutions; e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected. **4.1.2.2 Resources** The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
I. Organization (continued): sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the Quality Assurance Program may take various forms provided that the persons and organizations assigned the Quality Assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the Quality Assurance Program at any location where activities subject to this Appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function.	**II. Basic and Supplementary Requirements 1 - Organization (completed)**		**4.1.2 Organization (continued)** **4.1.2.3 Management representative** The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system. NOTE 5. The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system. **4.1.3 Management review** The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such review shall be maintained (see 4.16).

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
II. Quality Assurance Program: The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a Quality Assurance Program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. The applicant shall identify the structures, systems, and components to be covered by the Quality Assurance Program and the major organizations participating in the program, together with the designated functions of these organizations. The Quality Assurance Program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.	**II. Basic Requirement 2 - Quality Assurance Program:** A documented Quality Assurance Program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.	**(b) Quality Assurance Program.** (1) A contractor shall develop a QAP by applying the Quality Assurance criteria specified in paragraph (c) of this section. A QAP shall include a discussion of how the criteria of paragraph (c) of this section will be satisfied. The criteria of paragraph (c) of this section shall be applied using a graded approach. The contractor shall use appropriate standards, wherever applicable, to develop and implement its QAP. (2) Within 180 days after May 5, 1994, a contractor shall submit to DOE for approval a current QAP and an implementation plan. (3) A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.	**4.2 Quality system** **4.2.1 General** The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system. **4.2.2 Quality system procedures** The supplier shall a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and b) effectively implement the quality system and its documented procedures. For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
II. Quality Assurance Program (continued): The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The applicant shall regularly review the status and adequacy of the Quality Assurance Program. Management of other organizations participating in the Quality Assurance Program shall regularly review the status and adequacy of that part of the Quality Assurance Program which they are executing.	**II. Basic Requirement 2 - Quality Assurance Program (continued):** The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained. Management of those organizations implementing the Quality Assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation.	**(b) Quality Assurance Program. (Continued)** (4) Implementation plans and QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made or directed by DOE.	**4.2 Quality system (continued)** **4.2.3 Quality planning** The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts: a) the preparation of quality plans; b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality; c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation; d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation; e) the identification of any measurement requirement involving capability that exceeds the known state.

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
II. Quality Assurance Program (completed)	**II. Basic Requirement 2 - Quality Assurance Program (completed)**	**(b) Quality Assurance Program. (completed)**	**4.2 Quality system (continued)** **4.2.3 Quality planning (continued)** of the art, in sufficient time for the needed capability to be developed; f) the identification of suitable verification at appropriate stages in the realization of product; g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element; h) the identification and preparation of quality records (see 4.16).

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
III. Design Control: Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components. Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	**II. Basic Requirement 3 - Design Control:** The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.	**Subpart B - Design [Reserved]** (ii) *Design*. Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.	**4.4 Design Control** **4.4.1 General** The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met. **4.4.2 Design and development planning** The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves. **4.4.3 Organizational and technical interfaces** Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed. **4.4.4 Design input** Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their

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III. Design Control (continued): The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specified design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.	**II. Basic Requirement 3 - Design Control (completed)**	**Subpart B - Design [Reserved] (completed)**	**4.4 Design Control (continued)** **4.4.4 Design input (continued)** selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements. Design input shall take into consideration the results of any contract review activities. **4.4.5 Design output** Design output shall be documented and expressed in terms that can be verified and validated against design input requirements. Design output shall: a) meet the design input requirements; b) contain or make reference to acceptance criteria; c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g., operating, storage, handling, maintenance and disposal requirements). Design output documents shall be reviewed before release. **4.4.6 Design review** At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted.

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III. Design Control (continued): Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.	**II. Basic Requirement 3 - Design Control (completed)**	**Subpart B - Design [Reserved] (completed)**	**4.4 Design Control (continued)** **4.4.4 Design review (continued)** Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16). **4.4.7 Design verification** At appropriate stages of design, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification measures shall be recorded (see 4.16). **4.4.8 Design validation** Design validation shall be performed to ensure that product conforms to defined user needs and/or requirements.

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IV. Procurement Document Control: Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a Quality Assurance Program consistent with the pertinent provisions of this appendix .	**II. Basic Requirement 4 - Procurement Document Control:** Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require Suppliers to have a Quality Assurance Program consistent with the applicable requirements of this Part (Part I).	**(iv) Documents and Records.** Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained. **(iii) Procurement.** Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.	
V. Instructions, Procedures, and Drawings: Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	**II. Basic Requirement 5 - Instructions, Procedures, and Drawings:** Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.		

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VI. Document Control: Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.	**II. Basic Requirement 6 - Document Control:** The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.		**4.5 Document and data control** **4.5.1 General** The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this International Standard including, to the extent applicable, documents of external origin such as standards and customer drawings. **4.5.2 Document and data approval and issue** The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents. This control shall ensure that: a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed; b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use; c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

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VI. Document Control (completed)	**II. Basic Requirement 6 - Document Control (completed)**		**4.5 Document and data control (continued)** **4.5.3 Document and data changes** Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

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VII. Control of Purchased Material, Equipment, and Services: Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant prior to installation or use of such material and equipment. This documentary evidence shall be retained at the nuclear power plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at internals consistent with the importance, complexity, and quality of the product or services.	**II. Basic Requirement 7 - Control of Purchased Items and Services:** The procurement of items and services shall be controlled to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.	**Subpart D - Material Management [Reserved]**	**4.7 Control of customer-supplied product** The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the customer (see 4.16). Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

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VIII. Identification and Control of Materials, Parts, and Components: Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required through-out fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.	**II. Basic Requirement 8 - Identification and Control of Items:** Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner which assures that identification is established and maintained.		**4.8 Product identification and traceability** Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation. Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

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IX. Control of Special Processes: Measures shall be established to assure that special processes, including welding, heat treating, and non-destructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	**II. Basic Requirement 9 - Control of Processes:** Processes affecting quality of items or services shall be controlled. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.		**4.9 Process control** The supplier shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following: a) documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality; b) use of suitable production, installation and servicing equipment, and a suitable working environment; c) compliance with reference standards/codes, quality plans and/or documented procedures; d) monitoring and control of suitable process parameters and product characteristics; e) the approval of processes and equipment, as appropriate; f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations); g) suitable maintenance of equipment to ensure continuing process capability. Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes

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IX. Control of Special Processes (completed)	**II. Basic Requirement 9 - Control of Processes (completed)**		**4.9 Process control (continued)** shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met. The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified. Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).

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X. Inspection: A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.	**II. Basic Requirement 10 - Inspection:** Inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.		**4.10 Inspection and testing** **4.10.1 General** The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures. **4.10.2 Receiving inspection and testing** **4.10.2.1** The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures. **4.10.2.2** In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided. **4.10.2.3** Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in

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X. Inspection (completed)	**II. Basic Requirement 10 - Inspection (completed)**		**4.10 Inspection and testing (continued)** **4.10.2.3 (continued)** order to permit immediate recall and replacement in the event of nonconformity to specified requirements. **4.10.3 In-process inspection and testing** The supplier shall: a) inspect and test the product as required by the quality plan and/or documented procedures; b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3 a). **4.10.4 Final Inspection and testing** The supplier shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements. The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

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X. Inspection (completed)	**II. Basic Requirement 10 - Inspection (completed)**		**4.10 Inspection and testing (continued)** **4.10.4 Final Inspection and testing (continued)** No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized. **4.10.5 Inspection and test records** The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13). Records shall identify the inspection authority responsible for the release of product (see 4.16).

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XI. Test Control: A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.	**II. Basic Requirement 11 - Test Control:** Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated. Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.		

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XII. Control of Measuring and Test Equipment: Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.	**II. Basic Requirement 12 - Control of Measuring and Test Equipment:** Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.		**4.11 Control of inspection, measuring and test equipment** **4.11.1 General** The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability. Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).

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XII. Control of Measuring and Test Equipment (completed)	**II. Basic Requirement 12 - Control of Measuring and Test Equipment (completed)**		**4.11 Control of inspection, measuring and test equipment (continued)** **4.11.1 General (continued)** Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.

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XIII. Handling, Storage, and Shipping: Measures shall be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.	**II. Basic Requirement 13 - Handling, Storage, and Shipping:** Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.		**4.15 Handling, storage, packaging, preservation and delivery** **4.15.1 General** The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product. **4.15.2 Handling** The supplier shall provide methods of handling product that prevent damage or deterioration. **4.15.3 Storage** The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals. **4.15.4 Packaging** The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

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XIII. Handling, Storage, and Shipping (completed)	**II. Basic Requirement 13 - Handling, Storage, and Shipping (completed)**		**4.15 Handling, storage, packaging, preservation and delivery (continued)** **4.15.5 Preservation** The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control. **4.15.6 Delivery** The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

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XIV. Inspection, Test, and Operating Status: Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.	**II. Basic Requirement 14 - Inspection, Test, and Operating Status:** The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.	**(iv) Inspection and Acceptance Testing.** Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained. (3) *Assessment* (i) *Management Assessment*. Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected. (ii) *Independent Assessment.* Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.	**4.12 Inspection and test status** The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used or installed.

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XV. Nonconforming Materials, Parts, or Components: Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.	**II. Basic Requirement 15 - Control of Nonconforming Items:** Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.		**4.13 Control of nonconforming product** **4.13.1 General** The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.
XVI. Corrective Action: Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformance are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the conditions is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.	**II. Basic Requirement 16 - Corrective Action:** Conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.		**4.14 Corrective and preventive action** **4.14.1 General** The supplier shall establish and maintain documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action. **4.14.2 Corrective action** **4.14.3 Preventive action**

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XVII. Quality Assurance Records: Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.	**II. Basic Requirement 17 - Quality Assurance Records:** Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.		**4.16 Control of quality records** The supplier shall establish and maintain documented procedures for identification, collection, indexing access, filing, storage, maintenance and disposition of quality records. Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data. All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
XVIII. Audits: A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the Quality Assurance Program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, shall be taken where indicated.	**II. Basic Requirement 18 - Audits:** Planned and scheduled audits shall be performed to verify compliance with all aspects of the Quality Assurance Program and to determine its effectiveness. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.		**4.17 Internal quality audits** The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited. The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).
		Subpart D - Material Management [Reserved]	**4.18 Training** The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16).

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
			4.19 Servicing Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.
			4.10 Statistical techniques **4.20.1 Identification of need** The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics. **4.20.2 Procedures** The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

10 C.F.R. Part 50 Appendix B	ANSI/ASME NQA-1-1994	10 C.F.R. § 830.120	ISO 9001
			4.3 Contract review **4.3.1 General** The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities. **4.3.2 Review** Before submission of a tender, or the acceptance of a contract or order (statement of requirements), the tender, contract or order shall be reviewed by the supplier to ensure that: a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance; b) any differences between the contract or order requirements and those in the tender are resolved; c) the supplier has the capability to meet the contract or order requirements. **4.3.3 Amendment to a contract** The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

APPENDIX C

OTHER QUALITY MANAGEMENT SYSTEMS

The following summary is provided with permission of the Center for Chemical Process Safety from the book *Integrating Process Safety Management, Environment, Safety, Health and Quality* (1996), pages 143–147.

OTHER QUALITY MANAGEMENT SYSTEMS

9.1. Introduction

There are many different management system frameworks that can be used for integrating PSM [Process Safety Management] and ESH [Environment Safety and Health]. All the concepts presented in this book can be applied to other systems or templates, and the frameworks of different Quality Management systems can even be combined. For example, someone might wish to use the basic elements of ISO 9004 plus a management of change element as their template.

◆ Hint

No single Quality Management system is the best choice for all applications; all have their advantages and disadvantages, and are generally based on the same concepts.

Some of the most well known Quality Management approaches are Total Quality Management, the ISO 9000 series, the draft ISO 14000 series, the Malcolm Baldridge National Quality Award criteria, the Deming Prize criteria and the European Quality Award. The ISO 9000 series has been used to illustrate the concepts of this book, and each of the other systems is described briefly below. It is important to remember that the approach suggested in this book is to draw from the framework provided by a Quality Management system, to look at internal (or external) best practices and to integrate these across an organization. This book does not advocate nor discourage certification or pursuit of a quality award.

9.2. Total Quality Management

Total Quality Management is not a management system in and of itself. Rather, it is a philosophy of process improvement that incorporates elements of:

1. understanding customer needs and relationships
2. obtaining data
3. using tools
4. empowering those who know a process best to fix it
5. understanding existing processes
6. finding gaps, bottlenecks and inefficiencies within a process
7. improving processes or creating them where they did not exist

8. developing and using both in-process and results-oriented measures
9. looking for new improvement opportunities within a process

TQM has frequently been used to focus on and improve processes in order to meet customer requirements, but not necessarily to look beyond processes for integration opportunities and organizational changes. Thus, it may need to be used in conjunction with another Quality Management system for the purposes of integrating PSM and ESH activities.

9.3. Malcom Baldridge National Quality Award

The criteria for the Baldridge award in some ways codify the concepts and tenets of TQM into a management system, by describing what an organization that practices TQM should look like. This is not a surprising outcome, as Dr. J. M. Juran was one of the individuals who worked with the National Institute of Standards and Technology on this award. Numerous companies have found that the criteria are useful for self assessment and the identification of obstacles to further continuous improvement, in some cases with additional motivation for change provided by the prize. The criteria provide a systematic description of the management elements that are needed to deliver quality to customers, and cover seven primary areas of evaluation:

- leadership (management support)
- information and analysis
- strategic quality planning
- personnel development and management
- management of process quality (how business processes are managed)
- quality and operational results (measurement)
- customer focus and satisfaction

The criteria themselves are concerned with not only the approach to Quality Management, but also the way in which that approach is implemented and the results that are achieved.

9.4. European Quality Award

This award is similar to the Baldridge award, but also considers the financial success of the company or organization. This additional area of evaluation can alleviate concerns about the real-world viability of companies that win quality awards, but it can also change the focus of the measure to being retrospective. Thus it may not really consider if a company is positioned for long term success through understanding and meeting its customers' needs.

The elements of this system are grouped into nine areas of evaluation:

- leadership
- people management
- policy and strategy
- resources
- processes
- people satisfaction
- customer satisfaction
- impact on society

- business results.

9.5. Deming Quality System

The grandfather of Quality Management systems, the Deming quality system tends to be more philosophical than practical in nature. It is less explicit than the Baldridge criteria, and the criteria for the related Deming Prize were designed to be applied by a small, well-trained group of auditors. Some of the concepts which recur throughout Deming's 14 points include:

- leadership
- operating under common objectives and purposes
- relationships
- removing barriers
- reducing reliance on inspection by doing things right
- continuous improvement—plan, do, check, act
- using tools
- on the job training

While Deming's work serves as the foundation of TQM, the Baldridge award and many other quality systems, it requires translation to turn his points into the elements of a management system. His points can be used as a simple checklist, but are hard to measure against or even to interpret consistently—making it difficult to use them as a diagnostic tool.

9.6. ISO 14001

Environmental management systems share the same basic concepts of both PSM and Quality Management Systems, however, they recognize a broader range of customers than is typical in Quality Management Systems. These might include the public around a facility, society as a whole and evolving societal needs. All of the available environmental management systems are designed to help measure, monitor and assess environmental performance. They offer a high level template or framework that is of use whether or not certification is sought.

The ISO 14000 series is still a draft international standard, but the environmental management systems specification document (ISO 14001) is expected to be approved in mid 1996[3]. The general guidance document is being renumbered from 14000 to 14004 for consistency with the approach used in developing the ISO 9000 series. ISO 14000 has been designed for consistency with ISL 9000 and recognizes that some organizations may choose to use ISO 9000 as their basic management system with a few minor modifications in focus in order to address the concerns unique to ISO 14000. While ISO 14000 does not address occupational health and safety management, it does offer a framework that could readily be extended to cover these and other safety activities, thereby supporting integration efforts.

[3] ISO 14011 is the core management systems specification document in the ISO 14000 series. This document has been published by ISO (September 1996). It has been adopted by the USA as an American National Standard.

The draft version of *Environmental Management Systems—Specification with guidance for use*, document ISO 14001, is organized into the following sections:

- general
- environmental policy
- planning
- implementation and operation
- checking and corrective action
- management review

The correspondence of this standard ISO 9001 is also given, and has been summarized in Exhibit 1-1 on page 8 of this book.

References

Bradley T. Gale with Robert Chapman Wood, Managing Customer Value*: creating quality and service that customers can see*, The Free Press, New York, NY, 1994.

ISO/DIS 14001, Draft International Standard, *Environmental Management Systems—Specification with Guidance for Use*, 1995.

William Scherkenbach, *The Deming Route to Quality and Productivity: Road Maps and Roadblocks*, CeePress Books, George Washington University, Washington, D.C., 1986.

APPENDIX D

EXAMPLES OF QUALITY ASSURANCE ISSUES IDENTIFIED IN THE BOARD'S STAFF REPORTS AND LETTERS, 1998–2000

Report Type	Date	Author	Issue(s) Identified
Hanford Weekly	4/14/2000	Sautman/Stokes	Tank Farm Welding QA
SAC I Weekly	4/5/2000	Barton	Welding QA
SAC III Weekly	4/4/2000	Tontodonato	SRS Bagless Transfer System QAP
SRS Weekly	3/31/2000	Keilers/Davis	Bagless Transfer System QA
SAC I Weekly	3/22/2000	Barton	Slow Response on Software QA Reporting Requirement
SAC II Weekly	2/14/2000	McConnell	Pantex Fire Protection QA
SRS Weekly	2/11/2000	Keilers/Davis	Bagless Transfer System QA
SAC II Weekly	1/24/2000	McConnell	SNL TA-V Criticality Safety QA
Board Letter to USDOE	1/20/2000	Conway	Transmitting TECH-25
Hanford Weekly	12/3/1999	Arcaro/Sautman	Tank Farms Maintenance QA
Board Letter to AS/EH	12/1/1999	Conway (Yeniscavich/Linzau)	Welding QA
Board Letter to AS/DP	11/9/1999	Conway (Blackman)	Y-12 HF System Weld QA
SAC II Weekly	10/14/1999	McConnell	LANL Dynamic Experiments QA
SAC I Weekly	10/6/1999	Barton	Hanford SNFP QAP
SAC I Weekly	9/8/1999	Barton	Implementation of 10C.F.R. § 830.120
SRS Weekly	8/13/1999	Keilers/Davis	FB-Line Maintenance QA
Board Letter to AS/DP	7/20/1999	Conway (Hunt)	Y-12 Phase Out/Deactivation QA
Board Letter to AS/EM	7/8/1999	Conway (Grover/Wille)	Hanford SNFP HLW Disposal QA
SAC II Weekly	6/21/1999	McConnell	Y-12 HF System Procurement QA
RFETS Weekly	5/27/1999	Sautman	B771 Birdcage QA
Board Letter to USDOE	3/25/1999	Conway (Grover)	Hanford SNFP Procurement QA
SAC II Weekly	3/22/1999	McConnell	Software QA
Board Letter to USDOE	3/18/1999	Conway (Bamdad)	SRS Fire Protection QA
SAC II Weekly	3/8/1999	McConnell	Software QA
SAC II Weekly	3/1/1999	McConnell	Software QA (LANL TA-18)
Board Letter to AS/DP	1/15/1999	Conway (Jordan)	LANL TA-55 Fire Protection QA
SAC II Weekly	12/15/1998	McConnell	Welding QA (W56 Dismantlement NESS)
Board Letter to AS/DP	11/30/1998	Conway (Andrews/White/Bamdad)	Pantex Electrical System QA
Board Letter to AS/DP	8/24/1998	Conway (Yeniscavich)	Y-12 Welding QA
RFETS Weekly	7/31/1998	Sautman/Warther	B707 MAR Computer Program QA
RFETS Weekly	5/29/1998	Warther/Sautman	R94-1 PuSPS QA Requirements
Board Letter to USOE	3/11/1998	Conway (Davis)	SRS H-Canyon Software QA
SAC II Weekly	2/9/1998	McConnell	NTS AF&F/T&C QA on Subcritical Experiment Equipment

APPENDIX E
SUMMARIES OF SITE QUALITY ASSURANCE PROGRAMS

SUMMARY
SAVANNAH RIVER SITE QUALITY ASSURANCE PROGRAM

Purpose: Trace the requirements from 10 C.F.R. § 830.120 (i.e., the QA rule) through the Manuals of Practice to implementation functions and responsibilities.

Discussion: At the Savannah River Site, the Standards/Requirements Identification Document (S/RID) for Functional Area 2 covers QA and captures requirements from 10 C.F.R. § 830.120, DOE Order 414.1A, ASME NQA-1/1A/2A, Environmental Protection Agency (EPA) requirements, and other sources. In 1996, the Westinghouse Savannah River Company (WSRC) Quality Assurance Management Plan was written to document how WSRC implements 10 C.F.R. § 830.120. It addresses each criterion of the rule and discusses organizational roles and responsibilities. It is applicable to all WSRC facilities and operations.

QA is woven through the roughly four dozen WSRC manuals of practice used by all contractor organizations on site. This includes manuals on program management, procurement management, procurement specification, training and qualification, compliance assurance, startup testing, configuration management, conduct of engineering, independent assessments, etc.

Most of these manuals now reference the 1Q Manual, *Quality Assurance*, for details. The 1Q Manual includes sections on organization; the QA program; design control; procurement document control; instructions, procedures, and drawings; purchased items and services; process control; inspection; test control; measuring and test equipment; packaging, handling, shipping, and storage; item control and identification; nonconforming items; corrective action reports; QA records; audits; QA trending and improvements; software QA; and environmental QA.

In some cases, the 1Q Manual procedures are used directly. In others, organizations prepare job-specific implementing procedures. In those cases, the organizations are required to maintain a cross-reference to demonstrate alignment with the 1Q Manual.

An example is design control. Section 3-1 of the 1Q Manual describes the applicable scope (e.g., new or modified facilities). It defines the QA responsibilities of key individuals, including the Site Chief Engineer, the Division Chief Engineers, the Project Design Authority, and the Cognizant Quality Function. It lists requirements for ensuring quality in the design process (i.e., input, analysis, verification, interface, and output). It discusses requirements for records.

Organizationally, WSRC has a central QA Department under the WSRC ESH & QA Division Manager, who reports to the President, WSRC. Line divisions (e.g., Tritium, High Level Waste, Spent Nuclear Fuel, Nuclear Material Stabilization) each have their own internal QA programs, charged with implementing the 1Q Manual. Periodically, the QA programs in the line divisions and facilities are independently assessed by the Operations Evaluation Department, which is also part of ESH & QA. Often, this is done as part of Facility Evaluation Board reviews. Results are reported directly to the President, WSRC.

The table of contents of the 1Q Manual is included.

Attachment
Table of Contents of the WSRC 1Q Manual (6/15/2000)

Table of Contents of the WSRC 1Q Manual (6/15/2000) (Continued)

SUMMARY
ROCKY FLATS ENVIRONMENTAL TECHNOLOGY SITE QUALITY ASSURANCE

At RFETS, the requirements of 10 C.F.R. § 830.120 are invoked by DOE to Kaiser-Hill (KH) in the closure contract, Section J, Attachment B. The KH Quality Assurance (QA) Program Manual documents the roles, responsibilities, and methodologies to demonstrate compliance with DOE-Order 414.1 for non-nuclear facilities and 10 C.F.R. § 830.120 for nuclear facilities. The Quality Assurance Program (QAP) outlined in the Manual, describes how the QA requirements are met and the roles and responsibilities of KH and the principle subcontractors in implementing QA. The QAP is organized into ten criteria based on the requirements of 10 C.F.R. § 830.120 as follows:

- Program
- Personnel Training and Qualification
- Quality Improvement
- Documents and Records
- Work Processes (includes aspects of Engineering, Procurement, Fabrication, Installation, Operations, Maintenance, and Inspection)
- Design
- Procurement
- Inspection and Acceptance Testing (includes Configuration Management)
- Management Assessment
- Independent Assessment

The QA Program Manual identifies the primary implementation documents for each criterion and gives a consolidated listing implementation documents in Appendix 2 of the QA Program Manual. The QA Program Manual addresses each of the criteria of 10 C.F.R. § 830.120. Using the functional areas identified below, the following RFETS manuals and procedures provide detailed process instructions and guidance that implement the requirements of 10 C.F.R. § 830.120 as well other requirements identified in the QA Program Manual (this is not a comprehensive listing of implementing documents, only those of primary importance):

Equipment Design

Site Engineering Requirements Manual, MAN-027-SERM
Nuclear Safety Manual, MAN-018-NSM
Computer Software Management Manual, MAN-004-CSMM
Design Process Requirements, COEM-DES-210
General Drafting Standards, SX-300
Configuration Management Program Manual, MAN-095-CMPM

Procurement

Procurement Quality Assurance Requirements, PRO-572-PQR-001
Kaiser-Hill Company, L.L.C., Procurement Systems Volume I, II, and III
Supplier Quality Evaluations, 1-J55-ADM08.10
Acquisition Procedure for Requisitioning Commodities and Services, 1-W36-APR-111

Fabrication/Inspection

Inspection and Acceptance Testing Process, 1-PRO-072-001
Measuring and Test Equipment Management Manual, MAN-092-M&TEM
Integrated Work Control Program Manual, MAN-071-IWCP
Site Conduct of Operations Manual, MAN-066-COOP
Radiation Control Manual

Installation/Inspection

Integrated Work Control Program Manual, MAN-071-IWCP
Measuring and Test Equipment Management Manual, MAN-092-M&TEM
Measuring and Test Equipment Control Program, 3-M76-SOP-107
Inspection and Acceptance Testing Process, 1-PRO-072-001
Design Process Requirements, COEM-DES-210
Site Conduct of Operations Manual, MAN-066-COOP

Operations/Maintenance

Nuclear Safety Manual, MAN-018-NSM
Integrated Work Control Program Manual, MAN-071-IWCP
Site Conduct of Operations Manual, MAN-066-COOP
Training Program Manual, MAN-094-TPM
Site Training Implementation Matrix
Readiness Determination Manual, MAN-040-RDM
Kaiser-Hill Management Assessment Program, 3-W24-MA-002
Site Independent Oversight Manual, MAN-013-SIOM
Maintenance Program Manual
Radiation Control Manual
Occurrence Reporting Process, 1-D97-ADM-10.01

Configuration Management

Configuration Management Program Manual, MAN-095-CMPM
Integrated Work Control Program Manual, MAN-071-IWCP
Design Process Requirements, COEM-DES-210
Control of Processes, 1C20-QAP-09.01

SUMMARY
OAK RIDGE/Y-12 QUALITY ASSURANCE PROGRAM

At Y-12, the Quality Program Description (QPD), Y60-101PD, contains a list of requirements. It appears that the QPD contains all of the requirements from the 10 C.F.R. § 830.120 QA rule, as well as requirements from DOE Order 5700.6C. Other than listing the requirements, however, there is no forward linkage to manuals of practice or implementing procedures. Instead, the requirement matrix includes references back to Y-12 specific S/RID numbers.

The S/RID database appears to contain all the requirements from the 10 C.F.R. § 830.120 QA Rule. The database also contains information to link each requirement to specific implementing procedures. This database, however is not a useful tool in guiding one to do work. Its purpose is to be an evidence file to demonstrate that requirements are met in some fashion through implementing procedures.

Browsing Y-12's Command Media, it is possible to track some processes to implementing procedures. The procedures themselves will generally reference the specific S/RID numbers which they fulfill but one can't necessarily determine which part of the procedure meets each individual requirement.

Several Y-12 documents are listed for the categories below as well as some commentary on how well they flow requirements to procedures.

Engineering Design

- Y17-002PD, *Conduct of Engineering Program* - References the QPD. Includes high level descriptions with no flow to implementing procedures.

- Y17-001, *Engineering, Design and Construction* - References the QPD some flow to implementing procedures, but not from QA perspective.

- Y60-601, *Design* - References specific S/RIDs that are met and the QPD but no forward reference to implementing procedures.

Procurement

- Y30-802INS, *Basic Procurement Instruction* - References Y60-702, *Division Technical Review of Procurement Documents*, and Y60-705, *Acquisition, control, and Traceability of Safety SSCs*.

- Y60-701, *Procurement Quality* - References several other QA implementing procedures, also specific S/RIDS that are met.

- Y60-705, *Acquisition, control, and Traceability of Safety SSCs* - References several other QA implementing procedures, also specific S/RIDS that are met.

Inspection

- Y60-801, *Inspection/Test Control* - References several other QA implementing procedures, also specific S/RIDs that are met.

Operations/Maintenance

- Y14-001INS, *Conduct of Operations Manual* - Contains only an intro reference to a quality assurance manual (something that doesn't appear to exist at Y-12).

- Y18-004INS, *Work Control Process Manual* - No substantive QA references.

- Y18-003PD, *Maintenance Management Program* - Lists procurement S/RID and references procurement quality implementing procedures.

- Y18-039, *Field Calibration Program* - References the QA procedures for measuring and test equipment and its calibration (Y60-802, Y60-805, Y60-806).

- Y60-802, *Calibration and Control of Measuring and Test Equipment* - References S/RIDs that are met.

- Y60-805, *Out-of-Tolerance Measuring and Test Equipment (M&TE) Report and Evaluation* - References S/RIDs that are met.

- Y60-806, *External Calibration Services* - References Y60-802, *Calibration and Control of Measuring and Test Equipment.*

Configuration Management

- Y15-004PD, Configuration Management Program - References C.F.R. § 830.120, and the QPD. Also contains several references to both QA and non-QA implementing procedures.

QA specific Documentation at Y-12 (Y60 series)

- Y12-019, *Y-12 Quality Policy*
- Y60-101PD, *Quality Program Description*
- Y60-103, *Glossary*
- Y60-105, *Quality Planning for Major Missions*
- Y60-211, *Qualification of Assessment Personnel*
- Y60-301, *Control of Nonconforming Items (and Services)*
- Y60-302, *Request for Waivers or Deviations*
- Y60-331, *Lessons Learned Program*
- Y60-502, *Identification and Control of Items*
- Y60-503, *Handling, Storing, and Shipping*
- Y60-505PD, *Welding Program Description*
- Y60-551, *Stop Work/Restart Authority*

- Y60-601, *Design*
- Y60-701, *Procurement Quality*
- Y60-702, *Division Technical Review of Procurement Documents*
- Y60-704PD, *PAAA Procurements Program*
- Y60-705, *Acquisition, Control, and Traceability of Safety SSCs*
- Y60-707, *Supplier Evaluations*
- Y60-801, *Inspection/Test Control*
- Y60-802, *Calibration and Control of Measuring and Test Equipment (M&TE)*
- Y60-805, *Out-of-Tolerance Measuring and Test Equipment (M&TE) Report and Evaluation*
- Y60-806, *External Calibration Services*
- Y60-902, *Management Assessment*
- Y60-903, *Independent Assessment*
- Y60-904, *Surveillance*
- Y60-906, *Operational Readiness Reviews and Readiness Assessments*

SUMMARY
LAS ALAMOS NATIONAL LABORATORY QUALITY ASSURANCE PROGRAM

The Quality Assurance Rule. A Laboratory Performance Requirement (LPR), LPR 308-00-00, *Performance Requirement*: *Quality*, commits Las Alamos National Laboratory (LANL) to the requirements of 10 C.F.R. § 830.120 and DOE Order 414.1. This LPR requires LANL to maintain a current and official crosswalk that demonstrates the system by which the 10 criteria of 10 C.F.R. § 830.120 are translated into institutional requirements. (See attachment dated June 7, 2000.) When LPRs, Laboratory Implementation Requirements (LIRs), and other relevant institutional requirements documents are revised or developed, they are reviewed against the 10 criteria to ensure that quality performance criteria are met.

This approach has been accepted by DOE's Office of Enforcement and Investigation, as well as by the contracting officer. It helps ensure that new and revised LIRs and other requirements documents meet the quality performance criteria. However:

- Not all negotiated agreements have, as yet, resulted in LIRs. For example, LIRs do not yet cover procurement.

- In some areas, LIRs are not adequate in scope. For example, there is no list of codes and standards for the various kinds of safety-class and safety-significant structures, systems, and components. In addition, there is no accompanying requirement that architect-engineering firms hired to design defense nuclear facilities incorporate such codes and standards.

Manuals of Practice. LANL distinguishes between "facility work" and "non-facility work." Facility work is defined by LANL as "any combination of erection, installation, assembly, disassembly, construction, demolition, or fabrication activities involved in creating a new facility or in maintaining, altering, adding to, decontaminating, decommissioning, or rehabilitating an existing facility." Non-facility work includes research, development, testing, demonstration and limited-scale production. The following comments apply to facility work.

- **Equipment Design**—Equipment design is implicitly included in LIR 220-01-01.3, *Construction Project Management*, which does require design reviews. However, it is not clear that design reviews are required for equipment design. In addition, as noted above, specific codes and standards are not required for safety-class and safety-significant structures, systems, and components.

- **Procurement**—LIR(s) have yet to be developed for procurement.

- **Fabrication/Inspection**—A graded approach is permitted for facility work per LIR 230-01-02, *Graded Approach for Facility Work*. There are four gradations, called management levels, as follows:

  Management Level 1 (ML1) - Rigorous application of applicable codes, standards, procedural controls, verification activities, documentation requirements and formalized maintenance program. Could include facility

work for which independent review and management approvals for such things as design verification, procurement, fabrication, installation, assembly, and construction are considered essential.

Management Level 2 (ML2) - Selective application of applicable codes, standards, procedural controls, verification activities, documentation requirements, and formalized maintenance program (i.e., certain limited control measures). Could include facility work that may require independent review, management approval, and verification of design outputs, surveillance during procurement, fabrication, installation, assembly, and construction.

Management Level 3 (ML3) - Application of appropriate codes, standards, procedural controls, verification activities, and documentation requirements that are consistent with recognized industry practices. Could include facility work that is normally manufactured, installed, assembled, and/or constructed in accordance with recognized codes and standards.

Management Level 4 (ML4) - No formal management controls required, follow standard policy and procedures (i.e., activities where codes and standards are not applicable).

The choice of management level is at the discretion of the facility manager.

Per LIR 230-03-01.1, *Facility Management Work Control*, acceptance criteria are required for Management Levels 1 and 2.

! **Installation/Inspection**—Again, per LIR 230-03-01.1, *Facility Management Work Control*, acceptance criteria are required for Management Levels 1 and 2.

! **Operation/Maintenance**—LIR 230-04-01, *Laboratory Maintenance Management Program*, establishes a graded approach to maintenance requirements.

! **Configuration Management**—LIR 240-02-01.2, *Facility Configuration Management*, addresses configuration management.

SUMMARY
LAWRENCE LIVERMORE NATIONAL LABORATORY QUALITY ASSURANCE PROGRAM

Rule Implementation of the Quality Assurance. Lawrence Livermore National Laboratory (LLNL) has instituted a QA program that presumably reflects the requirements of 10 C.F.R. § 830.120. (See attachment dated March 1998.) The LLNL Implementation Plan espouses a risk-based graded approach to each of the nuclear facilities, so risk is regarded as the primary consideration in determining to what extent QA criteria are applied. Ten criteria are specified, which pertain to:

- Quality Assurance Plans
- Personnel Training and Qualification
- Quality Improvement
- Documents and Records
- Work Processes
- Design
- Procurement
- Inspection and Acceptance Testing
- Management Assessment
- Independent Assessment

DOE has not formally approved the March 1998 update of the LLNL QA Plan and QA Implementation Plan. The last formal DOE approval was in 1995. The updates were not formally approved because they were considered to be minor changes, and DOE Oakland Office (DOE-OAK) had approved them by 120-day default. DOE-OAK is working with LLNL to obtain a new update to the QA Plan and Implementation Plan submitted to DOE-OAK for approval.

A related issue previously noted by the staff is that Work Smart Standards related to the design of safety-class and safety-significant instrumentation and control (I&C) systems do not exist. The lack of standards in this area may point to more generic problems in defining key systems and their associated QA requirements. This deficiency (focused solely on I&C systems) is now being acted upon by LLNL, as articulated in a corrective action plan that has been submitted to DOE-OAK for approval.

Manuals of Practice. Any work done at LLNL must be done under either an Operational Safety Plan (OSP) or Facility Safety Plan (FSP). Both types of plans are to specify equipment and/or structures that fulfill some safety function, and mention is made of QA program requirements. For example, the manual specifying the necessary actions for QA with regard to OSPs states:

> **6.0 Maintenance, Inspections, and Quality Assurance**
> If maintenance, inspections, or quality assurance activities are necessary to maintaining the required controls, this section shall be added to discuss or reference the following:
>
> - Identify the safety systems associated with the operation for which failure to provide preventive maintenance could significantly increase the risk of injury, illness, loss or

damage of property (including programmatic equipment), or impact on the environment. Examples include interlocks, alarms on temperature sensors, hoods and filters, or scrubbers used in chemical operations.

- Specify the required maintenance to ensure these protective systems continue to function as designed, and identify the person responsible for conducting the maintenance. Additional guidance is provided in Section 4 of the LLNL Maintenance Program Guidance Manual. Refer to existing maintenance plans and programs where they exist.

- For the components and systems identified in Section 4 of the OSP as being critical to ES&H, state the methods for ensuring the quality of these systems (i.e., the schedule of tests, surveys, and inspections that will be performed on components or systems important to safety and environmental protection). Refer to existing, relevant quality assurance plans and procedures or to applicable sections of the FSP. Refer to the "LLNL Quality Assurance Program" in Volume IV of the ES&H Manual for additional guidance.

Equipment Design. The work smart standards refer to DOE Order 420.1, which identifies design requirements for nonreactor nuclear facilities and contains language requiring a QA program that satisfies 10 C.F.R. § 830.120 for safety structures, systems, and components. These requirements are in turn to be reflected in the OSPs and FSPs.

Procurement. No specific manual has been identified at this time, but the ISM System Phase I/II Verification Review at the Superblock report states: "Business management systems are integrated with the programs and with line management's safe conduct of work but could be more tightly integrated with the work change control process." The QA implications of this comment may indicate an area for improvement.

Fabrication/Inspection. No specific manual has been identified at this time.

Installation/Inspection. No specific manual has been identified at this time.

Operation/Maintenance. The LLNL *Maintenance Implementation Plan for Nonreactor Nuclear Facilities* establishes a graded approach for maintenance activities.

Configuration Management. No specific manual has been identified at this time.

SUMMARY
IDAHO NATIONAL ENGINEERING AND ENVIRONMENTAL LABORATORY (INEEL) BECHTEL BWXT, IDAHO'S 10 C.F.R. § 830.120 REQUIREMENTS FLOWDOWN

The following material is extracted from various contractual documents prepared by Bechtel BWXT Idaho, the Management and Operation contractor.

Flowdown of QA requirements at Bechtel BWXT Idaho (BBWI) can be depicted at three levels: (1) source requirements documents, (2) management basis documents, and (3) implementing procedures. Figure E-1 depicts these three levels. Documents within the company are constructed to meet external source requirements documents, such as regulations (10 C.F.R. § 830.120), and DOE orders; and internal corporate policies, company self-imposed standards, and management direction. Implementation of the QA program is through the following documents:

- Quality Assurance Program Requirements Document (QAPRD)—Describes the QA program that incorporates external quality requirements and internal policies.

- Quality Assurance Program Document (QAPD)—Identifies QA program requirements and guidance.

- Quality Assurance Program Plan—Specifies unique program or project customer requirements not addressed in the QAPD and its implementing procedures.

- Quality Assurance Project Plan—Identifies requirements to achieve data quality objectives for environmental activities.

- Implementing documents—Controlled documents that prescribe processes (a sequence of actions) to be performed to achieve a desired outcome. Implementing documents may apply to the entire company, an organization, a program, or a project. Those presented in Table E-1 are company-wide.

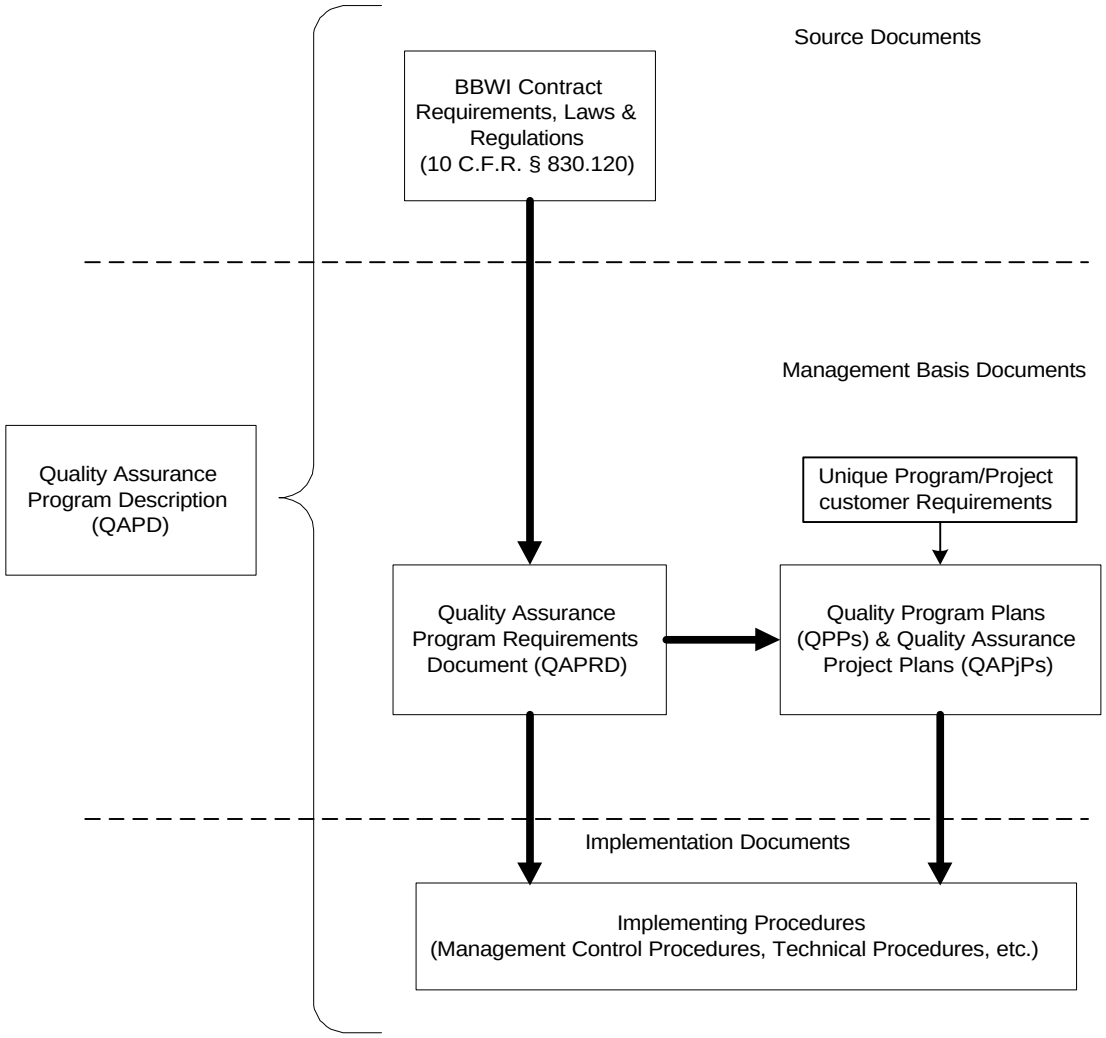


Figure E-1 - Requirement Flowdown, Bechtel, BWXT Idaho

Note: This table establishes the flowdown of requirements from the 10 C.F.R. § 830.120 source document to Bechtel BWXT Idaho institutional-level procedures. Institutional-level procedures encompass Management Control Procedures (MCPs), Program Description Documents (PDDs), Program Requirements Documents (PRDs), Plans (PLNs), Lists (LSTs), Guides (GDEs), Standards (STDs), and Technical Procedures (TPRs). Performer functions and responsibilities are delineated in the documents. Titles of the company manual volumes are presented on the last page.

Table E-1
REQUIREMENTS FLOWDOWN – 10 C.F.R. § 830.120, QUALITY ASSURANCE

10 C.F.R. § 830.120 Source Document Section/Paragraph	**BBWI Institutional Documents**	
	Company Manual/Document No.	**Section/Chapter**
(a) (1) (i) - Conduct work in accordance with 10 C.F.R. § 830.120 criteria.	13A - PDD-1 Stand-alone document - PLN-146	QA Program Description, Entire Document Implementation Plan for 10 C.F.R. § 830.120 QA Requirements
(a) (1) (ii) - Approval of QAP by DOE.	13A - PDD-1	QA Program Description, Section 2.1
(a) (1) (iii) - Implement the QAP.	13A - PDD-1	QA Program Description, Entire Document
	13A - PRD-101 Various company manuals and procedures	QA Program Requirements Document, Entire Document (See criteria listings below)
(b) (1) - Develop QAP applying 10 criteria, discuss how criteria are satisfied using a graded approach and use of appropriate standards.	13A - PDD-1	QA Program Description - Entire Document & especially Sections 2.1.3 (graded approach) and 5 (standards)
	13 A - PRD-101	QA Program Requirements Document - Entire Document
(b) (2), (3) & (4) – Submit QAP and implementation plan and receive approval.	13A - PDD-1 13D - MCP-551	QA Program Description - Section 2.1 QA and Oversight Procedure Control – Section 4.5
(c) (1) (i) - Criterion 1, Program	13A - POL-5 13A - PDD-1 13A - PDD-19 13A - PRD-101 13B - PLN-146	QA QA Program Description Integrated Requirements Management Program QA Program Requirements Document Implementation Plan for 10 C.F.R. § 830.120 QA

10 C.F.R. § 830.120 Source Document Section/Paragraph	BBWI Institutional Documents	
	Company Manual/Document No.	Section/Chapter
		Requirements
	13C - PLN-191	Owner/User Pressure Vessel Inspection Program
	1 - LST-1	List of Functional Areas and Functional Area Managers
	13B - MCP-540	Graded Approach & Quality Level Assignment
	14 - MCP-553	Stop Work/Shut Down Action
	13B - MCP-561	Quality Program Plan/QA Project Plan Development
	13B - MCP-2446	Nuclear Facility List Control
	13B - MCP-2447	Requirements Management
	10B - MCP-3740	Controlling Lists of Non-Nuclear Radiological & Other Industrial Facilities and Facility Managers
(c) (1) (ii) - Criterion 2, Personnel Training & Qualification.	12 - Training and Qualif. Manual	Training and Qualification Procedures
	10A - MCP-53	Qualifying Registered Professional Engineers for ASME Section III Division 1 & 2 Certifying Activities
	13D - MCP-196	Training, Qualification & Certification of Auditors/Lead Auditors
	13B - MCP-535	Inspection and Non-destructive Examination Personnel Certification
	9 – MCP-2983	Required Reading
	Stand Alone Document – STD-105	QA Training and Qualification
	10B - STD-1109	Nuclear Facility Manager Qualification
(c) (1) (iii) - Criterion 3, Quality Improvement	13B - POL-12	Lessons Learned (Policy)
	9 - MCP-190	Event Investigation and Occurrence Reporting
	13B - MCP-192	Lessons Learned Program
	13B - MCP-538	Control of Nonconforming Items
	14A - MCP-553	Stop Work Authority
	13B - MCP-598	Deficiency Screening & Resolution
	13B - MCP-2547	Price-Anderson Deficiency Reporting
	3 - MCP-2699	Documenting Cost Savings and Productivity Improvements
	13D - MCP-3521	Trending Center
(c) (1) (iv) - Criterion 4, Documents and Records	1 - PDD-11	Records Management
	1 - PDD-18	Document Management Control System (DMCS)
	1 - PRD-111	Records and Forms Management
	1 - PRD-138	Document Management
	1 - GDE-4	Data Management Practices Guide
	10A - GDE-59	Computer System Change Control
	1 - LST-9	INEEL Uniform File Codes
	1 - MCP-109	Releasing DMCS Controlled Documents
	1 - MCP-110	Distributing DMCS Documents
	1 - MCP-118	Identifying Controlled Documents

10 C.F.R. § 830.120 Source Document Section/Paragraph	BBWI Institutional Documents	
	Company Manual/Document No.	**Section/Chapter**
	1 - MCP-135	Creating, Modifying and Canceling Procedures and Other DMCS-Controlled Documents
	1 - MCP-160	Transfer and Retrieval of Inactive Records to/from Records Holding Area
	13D - MCP-551	QA & Oversight Procedure Control
	1 - MCP-556	Forms Management
	1 - MCP-557	Managing Records
	13D - MCP-2386	QA & Oversight Branch Records Control
	13D - MCP-2491	Redlining Drawings & Specifications
	10A - MCP-3573	Validating, Controlling, Using & Revising Vendor Data
	10A - MCP-3630	Computer System Change Control
	1 - STD-1	Procedure Writing Standard
	13B - STD-2	Standard for Program Requirements Documents
	1 - STD-8	Management Control Procedure Writing
	1 - STD-9	Technical Procedure Writing
	Stand Alone Document - STD-11	Drawing Requirements Standard
(c) (2) (i) - Criterion 5, Work Processes	7 - PRD-176	Management of Construction Projects
	6 - PRD-177	Maintenance Management Program Requirements
	9 - PRD-185	Conduct of Operations
	13B - MCP-37	Control of Special Processes
	18 - MCP-244	Chain-of-Custody, Sample Handling, & Packaging for Comprehensive Environmental Response, Compensation, and Liability Act Activities
	10A - MCP-550	Software Management
	9 - MCP-1059	Lockouts and Tagouts
	13D - MCP-2387	Quality Engineering Review
	13B - MCP-2391	Calibration Program
	2 - MCP-2474	Material Control and Inventory Management
	Calibration. Services Procedures Manual (CSPM) CSPM-FWD-6	Calibration Services Policy Statement
	CSPM - MCP-2492	Standards and Calibration Laboratories (S&CL) Operation
	CSPM - MCP-2493	S&CL Status Labels and Seals
	CSPM - MCP-2494	S&CL Handling, Transportation, Storing & Using M&TE
	CSPM - MCP-2495	S&CL Monitoring Program
	CSPM - MCP-2496	S&CL Overcheck Program
	CSPM - MCP-2497	Spill Plan for the S&CL
	CSPM - MCP-2498	S&CL Personnel Qualifications
	CSPM - MCP-2499	Hazardous Material/Equipment Control

10 C.F.R. § 830.120 Source Document Section/Paragraph	BBWI Institutional Documents	
	Company Manual/Document No.	Section/Chapter
	CSPM - MCP-2502	S&CL Calibration Intervals
	CSPM - MCP-2503	S&CL Adequacy of Measurement Process
	CSPM - MCP-2504	S&CL Updating and Interval Extension Policy
	CSPM - MCP-2505	S&CL Records Management
	CSPM - MCP-2506	S&CL CARE (Computer Advanced Maintenance & Equipment) Management System
	CSPM - MCP-2508	Electronic Equipment Pool Operation
	17 - MCP-2669	Hazardous Material Shipping
	17 - MCP-2670	Motor Carrier Operations
	17 - MCP-2676	Shipping General Commodities
	17 - MCP-2677	Import/Export Shipments of Hardware and Data
	6 - MCP-2795	Master Equipment List
	6 - MCP-2797	Maintenance Calibration Program
	18 - MCP-2864	Sample Management
	7 - MCP-2869	Project Turnover and Acceptance
	9 - MCP-2978	Control of Equipment and System Status
	9 - MCP-2979	Independent Verifications
	9 - MCP-2987	Equipment and Piping Labeling
	9 - MCP-3562	Hazard Identification, Analysis & Control of Operational Activities
	6 - STD-101	Integrated Work Control Process
	Stand Alone Document -STD-1090	DOE Standard - Hoisting and Rigging
	Stand Alone Document - No ID	INEEL Welding Manual (Vols. 1 & 2)
	Stand Alone Document -INEL-95/227	Guidelines for Identifying Suspect/Counterfeit Material Company-wide
(c) (2) (ii) - Criterion 6, Design	10A - PDD-12	Engineering Design
	10A - PRD-115	Configuration Management
	10A - PRD-181	Systems Engineering
	10A - GDE-6	Engineering Design Process Guides
	10A - GDE-59	Computer System Change Control
	10A - MCP-550	Software Management
	10A - MCP-2374	Engineering Analysis
	10A - MCP-2377	Development, Assessment & Maintenance of Drawings
	10A - MCP-2811	Engineering Change Control
	10A - MCP-2875	Maintaining Laboratory Notebooks
	10A - MCP-3534	Use of Professional Engineers
	10A - MCP-3630	Computer System Change Control
	10A - MCP-3767	Configuration Management & Design Recovery Planning
	10A - MCP-3772	Dedication Equivalency Evaluation of Commercial

10 C.F.R. § 830.120 Source Document Section/Paragraph	BBWI Institutional Documents	
	Company Manual/Document No.	Section/Chapter
		Grade Items
	10A - STD-7006	Marking Methods for Equipment, Components, and Materials
	10A - STD-107	Configuration Management Program
	10A - STD-7027	Specifications & Statements of Work
(c) (2) (iii) - Criterion 7, Procurement	4 - GDE-55	Ordering Data Guide for Quality Significant Purchases
	1 - MCP-558	Automatic Data Processing Asset Acquisition
	4 - MCP-590	Flow-down of Standard Procurement Quality Requirements
	4 - MCP-591	Supplier Evaluation & Qualification
	4 - MCP-592	Acquisition of Goods and Services
	13B - MCP-2489	Supplier Surveillance
	4 - MCP-3491	Acceptance of Procured Items & Services
	4 - MCP-3512	Procurement Planning
	4 - MCP-3513	Procurement Document Preparation
	4 - MCP-3514	Bid Proposal/Evaluation
	4 - MCP-3515	Control of Subcontract Changes
	4 - MCP-3516	Control of Supplier Generated Documents
	4 - MCP-3517	Supplier Performance Evaluation
	4 - MCP-9108	External Supplier Assessments
	4 - STD-1112	Standard Procurement Quality Requirements
(c) (2) (iv) - Criterion 8, Inspection and Acceptance Testing	13B - MCP-37	Control of Special Processes
	13B - MCP-195	NDE Equipment & Procedure Qualification
	13B - MCP-2482	Inspection for Conformance
	13D - MCP-2490	Construction Inspection Planning
	4 - MCP-3491	Acceptance of Procured Items & Services
	13D - TPR-4951	Density Testing, Nuclear Method
	13D - TPR-4952	Field Testing, Ready-Mix Concrete
	13D - TPR-4954	Field Testing - Grout
	13D - TPR-4955	Concrete Batch Plant Inspection
	13D - TPR-4970	Radiographic Examination
	13D - TPR-4971	Field Radiography Requirements
	13D - TPR-4972	Operation of Radiographic Facilities
	13D - TPR-4973	Maintenance of Radiography Equipment
	13D - TPR-4974	Manual Ultrasonic Examination
	13D - TPR-4975	Liquid Penetrant Examination
	13D - TPR-4976	Leak Test Procedure
	13D - TPR-4977	Magnetic Particle Examination
	13D - TPR-4978	Material Sorting Electronic Methods
	13D - TPR-4981	Visual Examination
	13D - TPR-4982	Manual Ultrasonic Examinations for Advanced Test Reactor Section XI Inservice Inspections
	13D - TPR-4984	Ultrasonic Digital Thickness Measurement
	13D - TPR-4985	Inservice Inspection Visual Examination
	13D - TPR-6304	Small Volume Pressure Change Leak Test

10 C.F.R. § 830.120 Source Document Section/Paragraph	BBWI Institutional Documents	
	Company Manual/Document No.	Section/Chapter
(c) (3) (i) - Criterion 9, Management Assessment	13B - MCP-8	Self-Assessment Process for Continuous Improvement
(c) (3) (ii) - Criterion 10, Independent Assessment	3 - MCP-130 18 - MCP-243 13B - MCP-552 10B - MCP-573 13D - MCP-589 4 - MCP-9108	Corporate Internal Audit Process Assessment of Analytical Laboratories Conduct of Independent Oversight Assessments Activities of the Nuclear Facilities Safety Committees QA Surveillance External Supplier Assessments

Company Manuals	
Volume No.	Title

1	General Administration and Information
2	Logistics and Property Management
3	Financial Operations
4	Procurement
5	Project and Cost Control
6	Maintenance
7	Project and Construction Management
8	Environmental Protection and Compliance
9	Operations
10A	Engineering and Research – Configuration Management, Engineering Design, Research and Development, Systems Engineering
10B	Engineering and Research – Safety Analysis, Criticality Safety
11A	Safeguards and Security Program – Management
11B	Safeguards and Security Program – Protection Program Operations
11C	Safeguards and Security Program – Information Security
11D	Safeguards and Security Program – Nuclear Materials Control and Accountability
11E	Safeguards and Security Program – Personnel Security
12	Training and Qualification
13A	Quality and Requirements Management – Program Documents
13B	Quality and Requirements Management – Procedures
13C	Quality and Requirements Management – Owner-User Pressure Vessel Quality Program
13D	Quality and Requirements Management Inspection/Test/Administrative Procedures
14A	Safety and Health – Occupational Safety, Fire Protection
14B	Safety and Health – Occupational Health
15A	Radiation Protection – INEEL Radiological Control
15B	Radiation Protection – Procedures
16	Emergency Preparedness
17	Waste Management
18	Closure Management

SUMMARY
HANFORD QUALITY ASSURANCE STATUS

The Project Hanford QAPD describes how the QA requirements in 10 C.F.R § 830.120 and DOE Order are implemented. Figure E-2 depicts the flowdown of requirements to work control documents. The QAPD addresses the high level requirements in the rule and Order. The following procedures provide additional requirements for implementing the rule's requirements (this is an illustrative list, not an all-inclusive list):

Engineering Design

HNF-MP-007	Systems Engineering Management Plan
HNF-PRO-1819	Project Hanford Management Contract Engineering Requirements
HNF-PRO-097	Engineering Design and Evaluation
HNF-PRO-259	Graded Quality Assurance
HNF-PRO-309	Computer Software Quality Assurance Requirements
HNF-PRO-709	Preparation and Control Requirements for Engineering Drawings

Procurement

HNF-PRO-123	Materials Requisition/Purchase Requisition/Contract Requisition Process
HNF-PRO-268	Control of Purchased Items and Services
HNF-PRO-301	Control of Suspect/Counterfeit Items
HNF-PRO-3144	Supplier Evaluation

Fabrication/Inspection

HNF-PRO-268	Control of Purchased Items and Services
HNF-PRO-301	Control of Suspect/Counterfeit Items
HNF-PRO-283	Control of Inspections
HNF-PRO-286	Test Control
HNF-PRO-297	Inspection, Test and Operating Status
HNF-PRO-1607	Visual Weld Inspection

Installation/Inspection

HNF-PRO-268	Control of Purchased Items and Services
HNF-PRO-301	Control of Suspect/Counterfeit Items
HNF-PRO-283	Control of Inspections
HNF-PRO-286	Test Control
HNF-PRO-297	Inspection, Test and Operating Status
HNF-PRO-1607	Visual Weld Inspection
HNF-PRO-1997	Construction Program Overview

Operations/Maintenance

HNF-PRO-052	Corrective Action Management
HNF-PRO-297	Inspection, Test and Operating Status
HNF-PRO-1607	Visual Weld Inspection
HNF-PRO-4294	Performance Indicator Process

Configuration Management

HNF-MP-013	Configuration Management Plan
HNF-PRO-224	Document Control
HNF-PRO-709	Preparation and Control Requirements for Engineering Drawings

The staff reviewed and compared the requirements of ASME NQA-1-1997, *Quality Assurance Requirements for Nuclear Facility Applications*, with Fluor Hanford's corporate *Quality Assurance Program Description* (HNF-MP-599) and the Plutonium Finishing Plant (PFP) specific *Quality Assurance Program Plan* (FSP-PFP-5-8, Volume 2, Section 15.1). The intent was to determine the extent to which the Fluor Hanford QA documents had incorporated the requirements and guidance outlined in the industry standard. The review focused on the requirements for the design, procurement, and inspection processes.

The QAPD defines the controls necessary to comply with the contractual requirements of 10 C.F.R. § 830.120, *Quality Assurance Requirements*, and DOE Order 414.1, *Quality Assurance*. The Quality Assurance Program Plan (QAPP) describes how PFP implements and complies with the applicable QA requirements of the Fluor Hanford QAPD. The QAPP does not contain specific or different design, procurement, or inspection criteria that apply exclusively to PFP, but lists procedures that implement the QAPD requirements at PFP. The QAPP essentially describes organizational and personnel responsibilities, administration of the QAPP, and implementing procedures.

Part 2, Section 6 ("Design") of the Fluor Hanford QAPD is very similar to Requirement 3 of NQA-1, *Design Control*. The major subsections on design input, design process, and design verification are in many cases repeated verbatim. It appears there are significant omissions, relative to the requirements of NQA-1 in the QAPD. The PFP QAPP lists five project-specific implementing procedures dealing with design and the requirements are applicable to 9 of 16 PFP organizations (e.g., technical support, radiological control, environmental compliance).

Part 2, Section 7 ("Procurement") of the Fluor Hanford QAPD is also very similar to the criteria of Requirements 4 and (parts of) 7 of NQA-1, *Procurement Document Control* and *Control of Purchased Items and Services,* respectively. All of the key procurement requirements of NQA-1 have been incorporated into the QAPD. The PFP QAPP lists two project-specific implementing procedures dealing with procurement, and the requirements are applicable to 13 of 16 PFP organizations (*not* applicable to surveillance, stabilization, or health and safety).

Part 2, Section 8 ("Inspection and Acceptance Testing") of the Fluor Hanford QAPD contains criteria described in Requirements 10, 12, and 14 of NQA-1, *Inspection, Control of Measuring* and *Test Equipment, and Inspection, Test, and Operating Status,* respectively. One area of potential weakness is the lack of direction on source verification and receipt inspection. These requirements are covered in Requirement 7 of NQA-1 but are not represented in the QAPD. The PFP QAPP lists three project-specific implementing procedures dealing with inspection, and the requirements are applicable to all 16 PFP organizations.

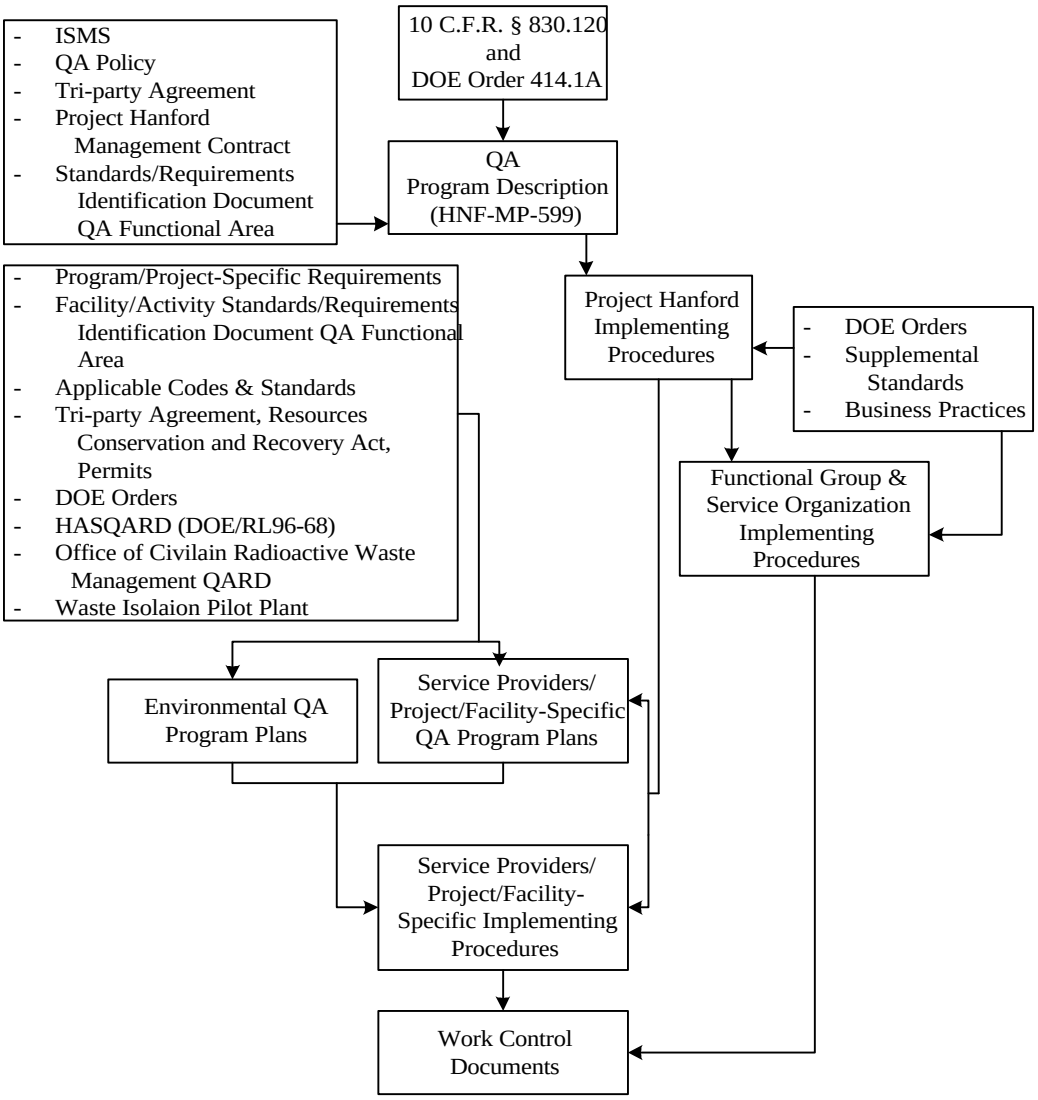
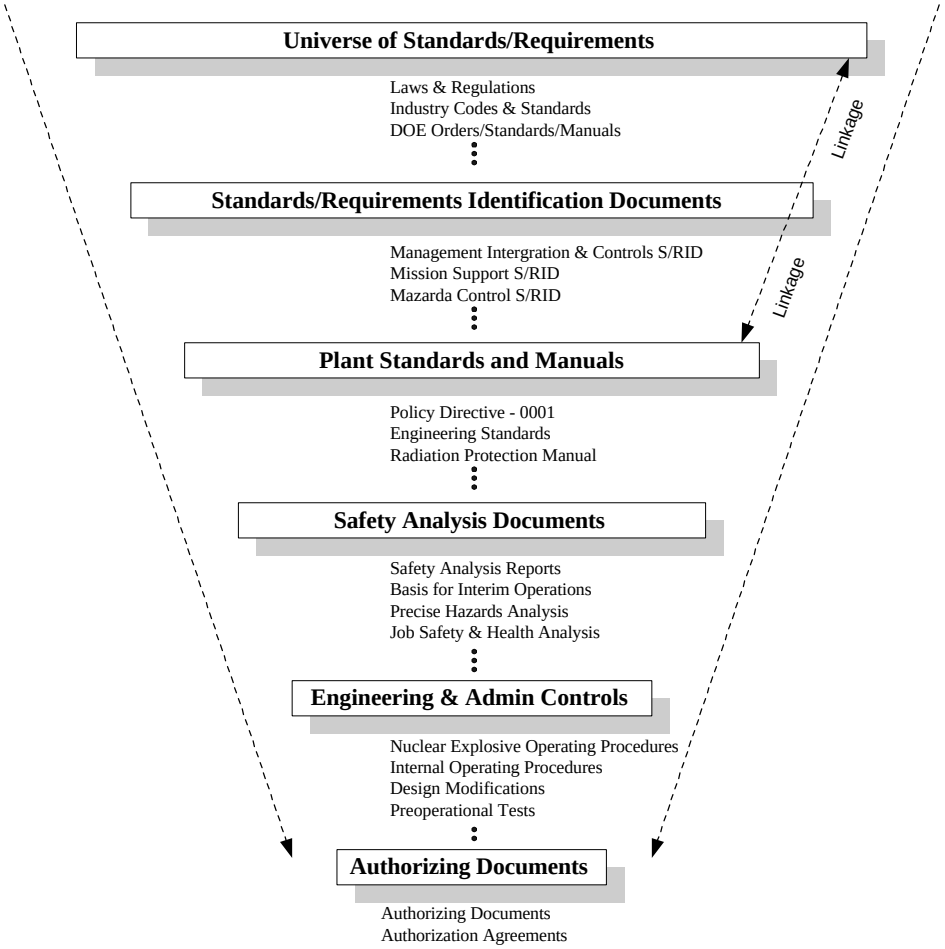


Figure E-2. Project Hanford QA Program Document Hierarchy

SUMMARY
FLOWDOWN OF QUALITY ASSURANCE AT THE PANTEX PLANT

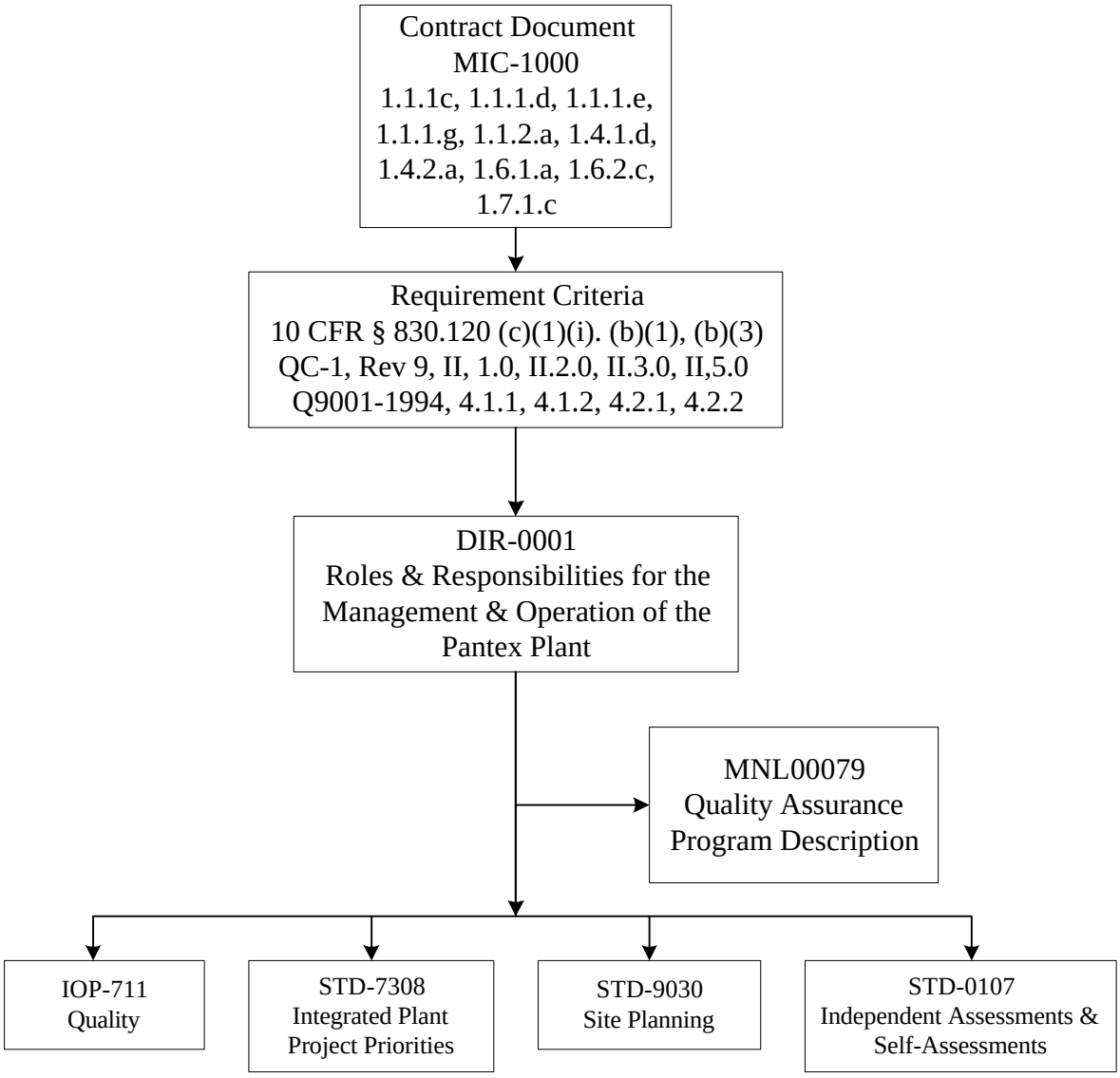
BWXT Pantex has a sitewide Quality Assurance Program that follows the tenets of 10 C.F.R. § 830.120, Quality Assurance Requirements, and also the DOE Albuquerque Field Office QC-1, Quality Criteria. These regulations/standards are adopted in their entirety by the highest tier of site Standards/Requirements Identification Documents, the Management Integration and controls (MIC) S/RID. (Specific subsections of C.F.R. § 830.120 are also called out in the Environmental Management Mission Support S/RID and the Off-Site Packaging and Transportation Hazards Control S/RID.)

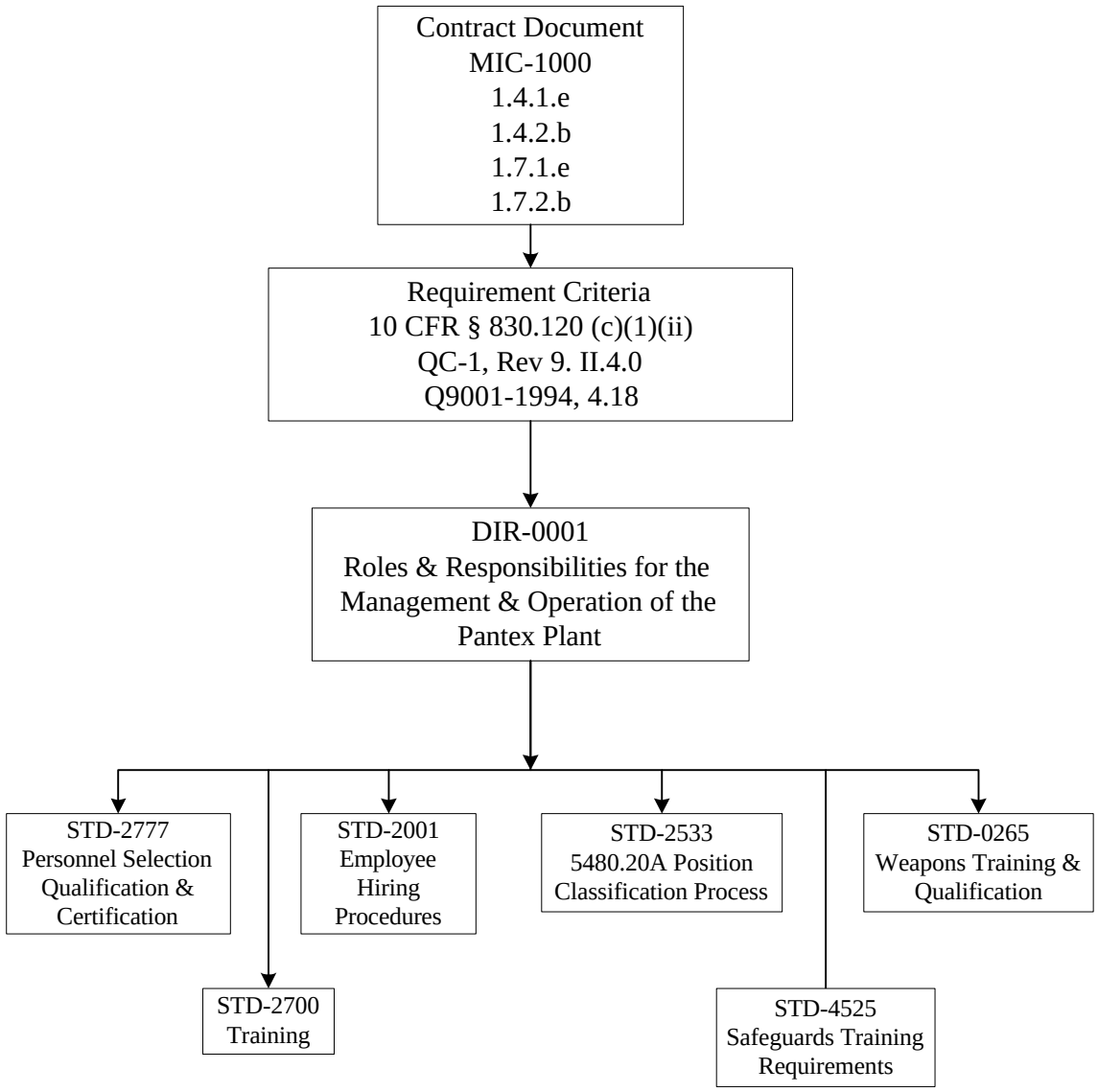
From the MIC S/RID, the various requirements of 10 C.F.R. C.F.R. § 830.120 flow down into the site manuals of practice. In general, the hierarchy of Pantex site documents is shown in the figure below. The chief site document defining the QA Program is MNL 00079, Pantex Plant Quality Assurance Program Description. Flowdown for each of the QA program requirements from C.F.R. § 830.120 is illustrated in the figures depicted on the following pages. These figures have been taken from MNL 00079. Comments identifying known errors or additional local standards and manuals are included with each.



10 C.F.R. § 830.120 (c)(1)(i): PROGRAM

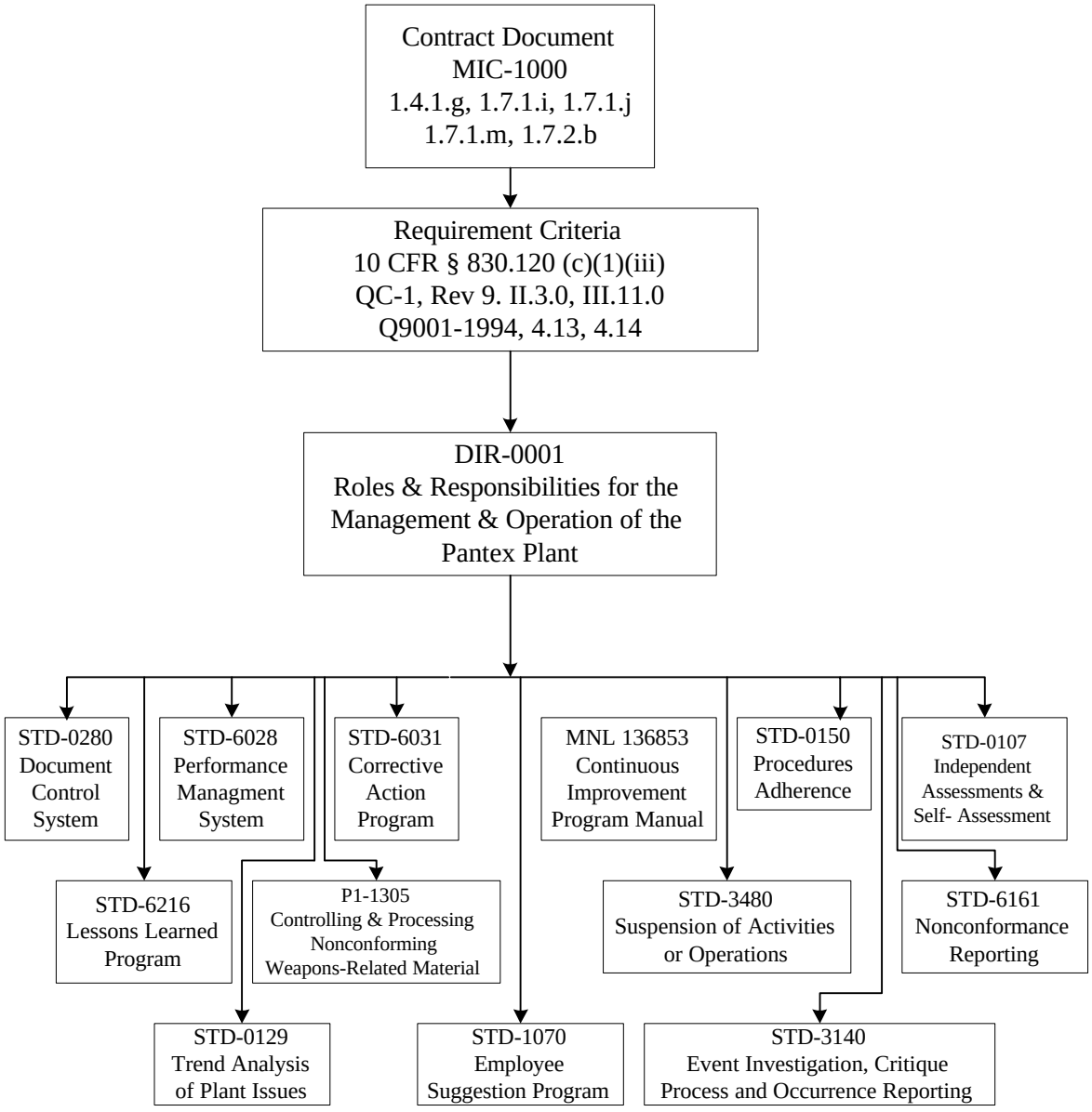
<u>Comments:</u> MICS/RID criterion 1.7.1.b was omitted from the top level requirements.





10 C.F.R. § 830.120 (c)(1)(ii): PERSONNEL TRAINING AND QUALIFICATION

Comments:
None

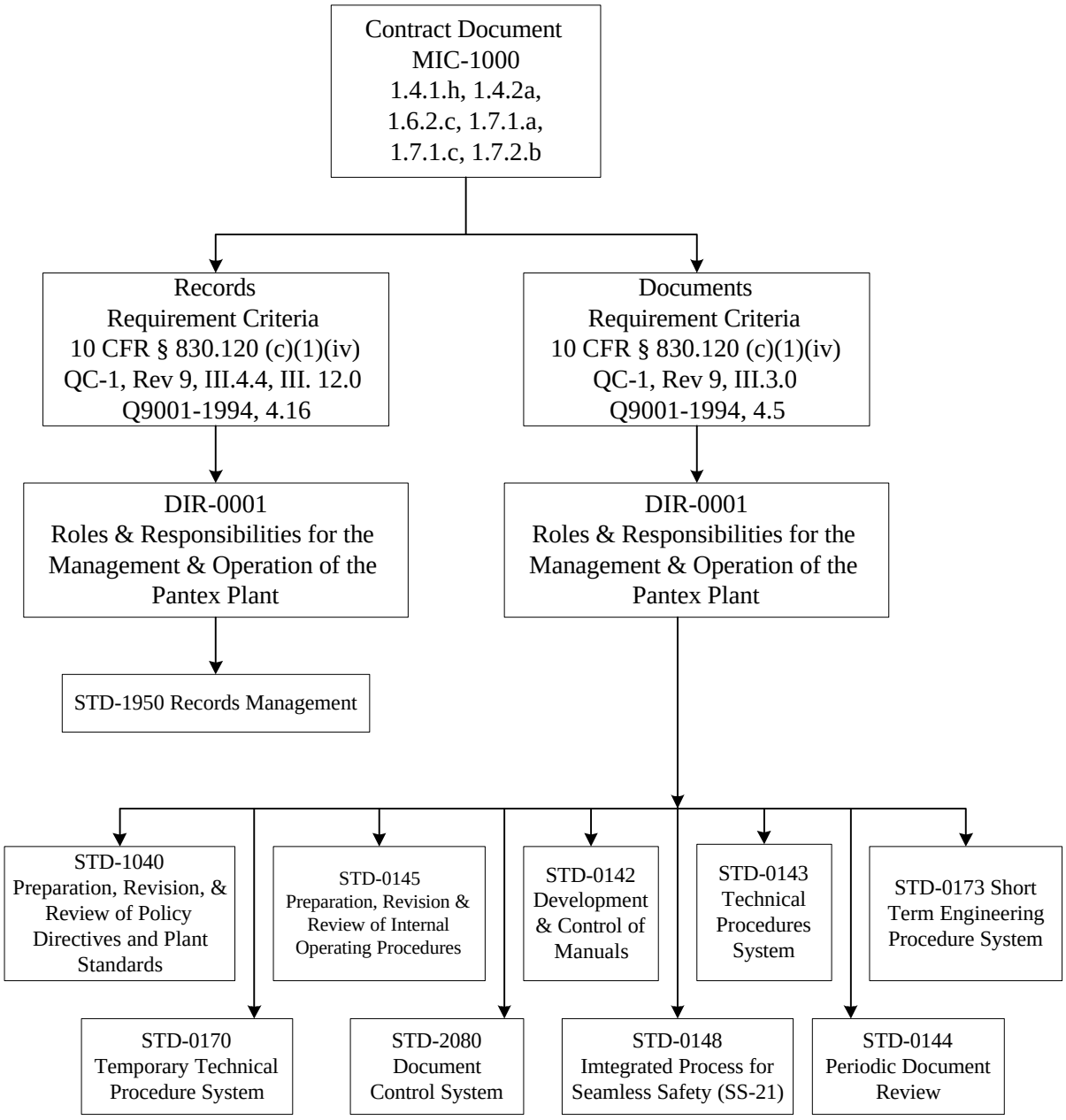


10 C.F.R § 830.120 (c)(1)(iii): QUALITY IMPROVEMENT

Comments:
None.

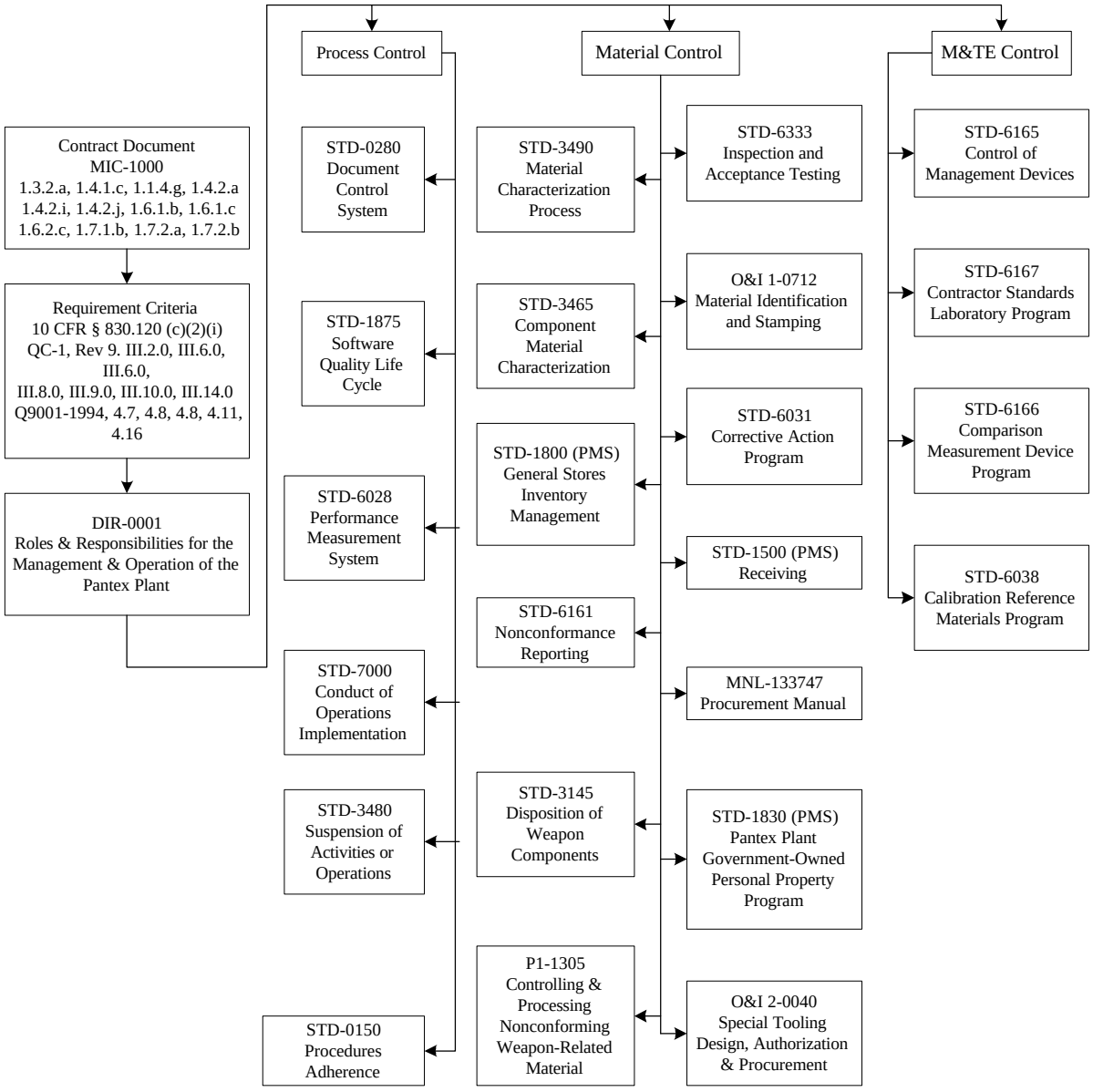
10 C.F.R. § 830.120 (c)(1)(iv): DOCUMENTS AND RECORDS

Comments:
None.



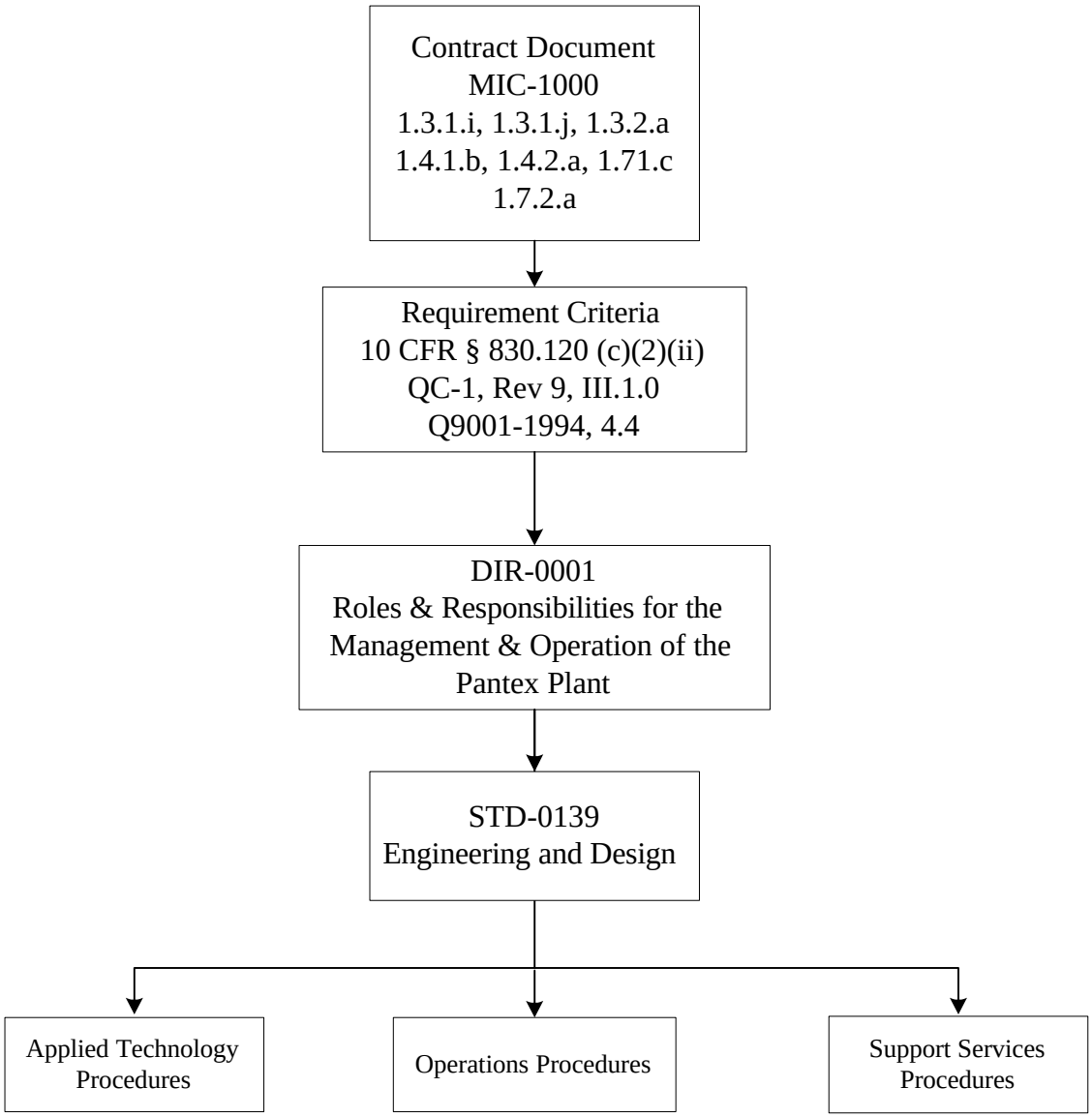
10 C.F.R. § 830.120 (c)(2)(i): WORK PROCESSES

Comments:
MIC S/RID criterion 1.3.1.k was omitted from the top level requirements
MIC S/RID criterion 1.7.1.b in the top level is incorrect – it should be 1.7.1.c.
MNL-FO-1106, *Maintenance Implementation Plan* was omitted from the list of site implementing documents



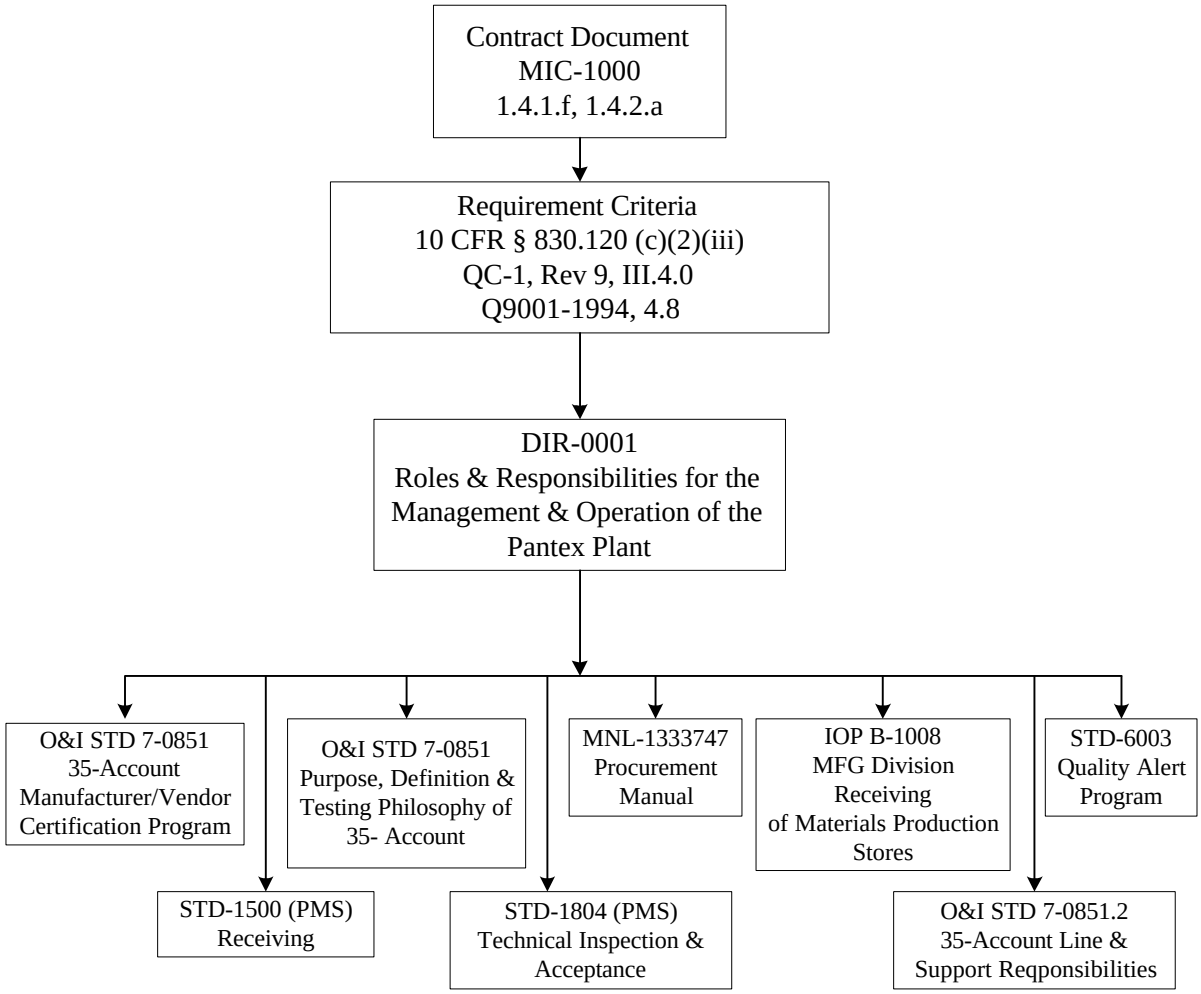
10 C.F.R. § 830.120 (c)(2)(ii): DESIGN

Comments:
MIC S/RID criterion 1.71.c in the top level requirements is a typo – it should read 1.7.1.c



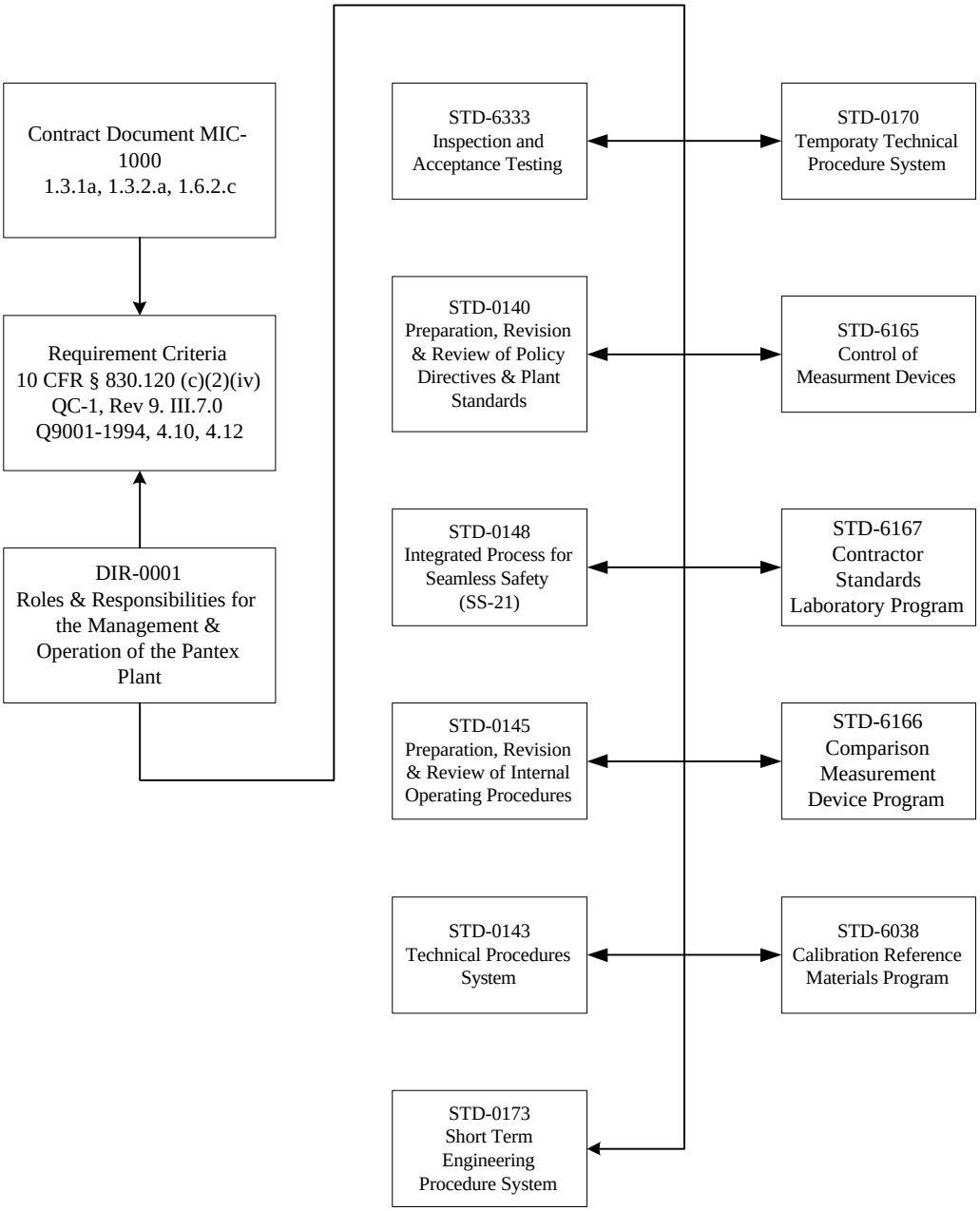
10 C.F.R. § 830.120 (c)(2)(iii): PROCUREMENT

Comments:
None.



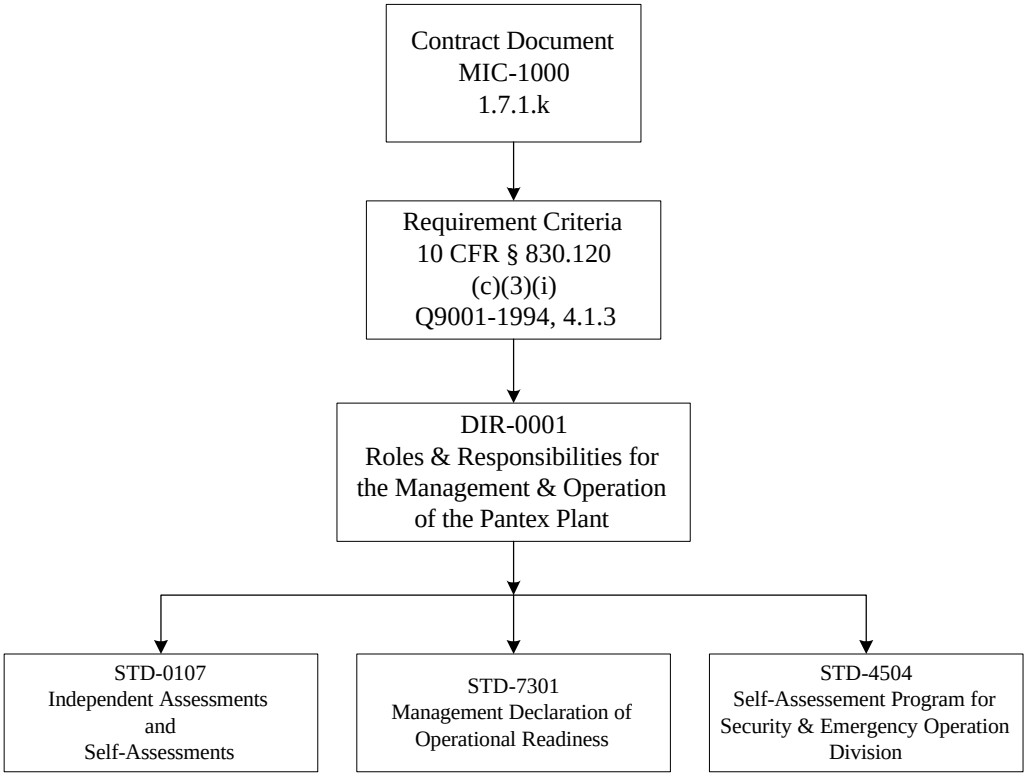
10 C.F.R. § 830.120 (c)(2)(iv): INSPECTION AND ACCEPTANCE TESTING

Comments:
The following have been omitted from the list of site implementing documents:
IOP E-8602, *Validation of Nuclear Criticality Safety Computer Programs*
IOP E-4203, *Tooling & Inspection Requirements Form*
O&I STD 7-0851.2, *35 Account*
O&I STD P7-0530, *Procedures for the Processing & Inspection of Parent Unit Parts*
STD 1804, *Technical Inspection & Acceptance*



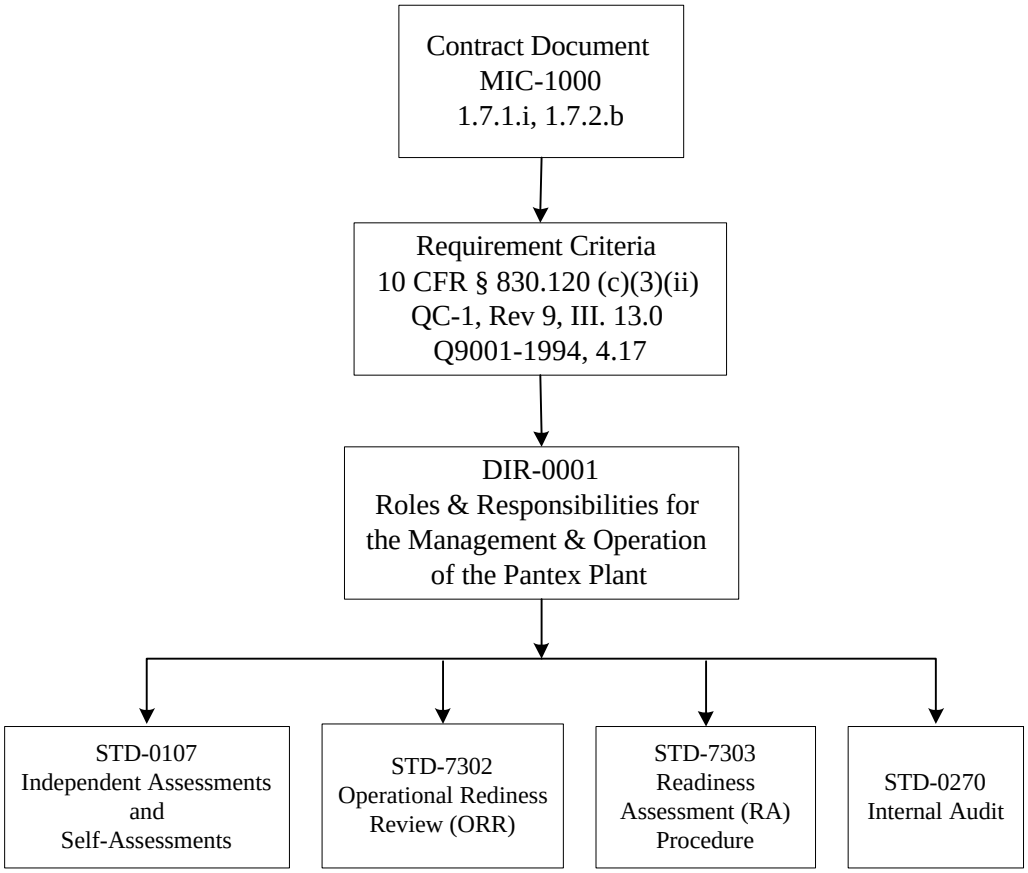
10 C.F.R. § 830.120 (c)(3)(i): MANAGEMENT ASSESSMENT

Comments:
The following have been omitted from the list of site implementing documents:
AT-IOP-80002, *Applied Technology Division Assessment Program*
AT-IOP-80024, *Applied Technology Division Performance Based Self-Assessment Program*
MNL-133747, *Procurement Manual*
STD-3008, *Annual Safety & Health Program Evaluation*
STD-3182, *Executive Safety Committee for Safety and Health Activities*
STD-3190, *Safety surveys of Facilities*
STD-3338, *Nuclear Explosives Safety*
STD-4321, *Fire Protection Assessments*
STD-4343, *Fire Department Building Inspection*



10 C.F.R. § 830.120 (c)(3)(i): INDEPENDENT ASSESSMENT

Comments:
The following have been omitted from the list of site implementing documents:
AT-IOP-80002, *Applied Technology Division Assessment Program*
AT-IOP-80024, *Applied Technology Division Performance Based Self-Assessment Program*
MNL-133747, *Procurement Manual*
STD-3008, *Annual Safety & Health Program Evaluation*
STD-3182, *Executive Safety Committee for Safety and Health Activities*
STD-3190, *Safety surveys of Facilities*
STD-3338, *Nuclear Explosives Safety*
STD-4321, *Fire Protection Assessments*
STD-4343, *Fire Department Building Inspection*



REFERENCES

Bank, J., 1992, *The Essence of Total Quality Management*.

Carr, D. K. and I. Letterman, 1993, *Excellence in Government*.

Center for Chemical Process Safety, 1996, *Guidelines for Integrating Process Safety Management, Environment, Safety, Health, and Quality*.

Defense Nuclear Facilities Safety Board, 2000, DNFSB/TECH-25, *Quality Assurance for Safety-Related Software at Department of Energy Defense Nuclear Facilities*.

Duncan W. J., and J. G. Van Matre, 1990, "The Gospel According to Deming: Is It really New?", *Business Horizons*, July–August.

Stevenson, J. D., 1992, *Quality Assurance in Nuclear Facilities Industry*, White Paper prepared for the Defense Nuclear Facilities Safety Board, January.

U.S. Department of Energy, 1994, *Total Quality Management Implementation Guidelines*, June.

U.S. Department of Energy, 1981, *A Safety Assessment of Department of Energy Nuclear Reactors*, DOE/US-005, March.

GLOSSARY OF ACRONYMS

AEC	Atomic Energy Commission
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASCE	American Society of Civil Engineers
ASME	American Society of Mechanical Engineers
BBWI	Bechtel BWXT Idaho
Board	Defense Nuclear Facilities Safety Board
C.F.R.	Code of Federal Regulations
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DOE-OAK	DOE Oakland Operations Office
EH-2	DOE Office of Independent Oversight
EPA	Environmental Protection Agency
ESH	Environment, Safety, and Health
FSP	Facility Safety Plan
GDEs	Guides
I&C	instrumentation and control
INEEL	Idaho National Engineering and Environmental Laboratory
ISO	International Standards Organization
ISM	Integrated Safety Management
KH	Kaiser-Hill
LANL	Las Alamos National Laboratory
LIRs	Laboratory Implementation Requirements
LLNL	Lawrence Livermore National Laboratory
LPR	Laboratory Performance Requirement
LSTs	Lists
M&TE	Measurement and Test Equipment
MCPs	Management Control Procedures
MIC	Management Integration and Controls
NASA	National Aeronautics and Space Administration
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
PDD	Program Description Documents
PFP	Plutonium Finishing Plant
PLNs	Plans
OSP	Operational Safety Plan
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QAPP	Quality Assurance Program Plan
QAPRD	Quality Assurance Program Requirements Document
QC	Quality Control

QAWG	Quality Assurance Working Group
QPD	Quality Program Description
S&CL	Standards and Calibration Laboratories
SMS	Safety Management System
S/RID	Standards/Requirements Identification Document
STDs	Standards
TPRs	Technical Procedures
TQM	Total Quality Management
WSRC	Westinghouse Savannah River Company