APPENDIX D

PROGRAMS OF OTHER AGENCIES, INDUSTRIES, AND FOREIGN COUNTRIES FOR THE ASSURANCE OF QUALITY

D.1 INTRODUCTION

This appendix reports the results of a study of the assurance of quality (AOQ) programs of five other U.S. government agencies and of NRC counterparts in six foreign countries. Section D.1 presents introductory material on the study's background, purpose and objectives, and technical approach. Conclusions and findings are presented in Section D.2. Section D.3 gives the significant findings from each program, and Section D.4 summarizes the studies of the domestic and foreign programs. References are provided in Section D.5. Appendix D contains two similar terms, "Assurance of Quality" (AOQ) and "Quality Assurance" (QA). The term "Quality Assurance" has been commonly used in recent years to connote a rather specific, single element in an overall management and/or regulatory process to provide both requisite quality and the assurance that it has been attained. Since this appendix addresses both the QA element and other related elements of these processes, the term "Assurance of Quality" has been used to distinguish between the overall process and the narrower, more specific part represented by "Quality Assurance."

D.1.1 Background

The complexity and extent of problems that have been identified in the past few years at some of the commercial nuclear power plants under construction in the U.S. have caused concern regarding the quality of the design and construction of these plants. Analyses of the experience at problem sites have identified three primary problem areas: 1) failure of the project management team to provide adequate management controls to prevent a significant breakdown in quality from occurring; 2) failure of the owners' quality assurance program to detect the breakdown in a timely manner and to obtain the appropriate corrective action; and 3) failure of the NRC's programs to recognize the true extent and nature of the problems (Dircks 1982).

In response to these problems, the NRC developed several initiatives aimed at bringing about effective improvements in the programs to assure quality. As a part of this overall effort, the NRC initiated a long-term review for continuing evaluation of quality and QA problems related to design, construction, testing and operation of nuclear power plants. Also included in this review is the evaluation of potential solutions to these problems and their impact on the adequacy of QA policies and programs.

D.1.2 Purpose and Objectives

The purpose of the study addressed in this appendix is to assist in the forumulation of the long-term direction of NRC AOQ policies and programs. This study is consistent with the direction provided the NRC by Congress in the

FY 1982-83 Authorization Act (Public Law 97-415, Section 13) to study alternatives for improving the quality assurance and quality control in the design and construction of nuclear power plants.

This study has three objectives:

- conduct a review of the AOQ programs and practices of the U.S. nuclear power industry; of selected private industries and associated regulatory agencies; and a limited review of the foreign nuclear power industry

- identify some AOQ program aspects and practices of these industries applicable to improving the U.S. nuclear power industry.

- determine where changes may be appropriate to improve the NRC AOQ program requirements and practices.

The scope of this study is limited to design-, construction- or fabrication-related activities of the industries and programs selected for review. Follow-on operational activities were not studied.

D.1.3 Technical Approach

At the initiation of this effort, an assessment plan was prepared to provide guidance in carrying out this study. This plan established a methodology for selecting industries to be studied, the content of the various reviews, and the format of the final report.

An important element of this study is the selection of the industries and programs to be examined. One organizational category of interest is nuclear endeavors that are not under NRC jurisdiction. This category includes the Department of Energy (DOE), the U.S. Navy (USN), and nuclear programs in foreign countries. A second organizational category of interest is nonnuclear endeavors that involve highly complex technology that requires high-quality standards in design and manufacture and that strives for low probability of failure because the consequences of failure may be substantial. This category includes aircraft manufacturing regulated by the Federal Aviation Administration (FAA), shipbuilding under both the USN and the Maritime Administration (MarAd), and spacecraft under the National Aeronautics and Space Administration (NASA).

Included in these categories are two subcategories. One is represented by situations where a government agency is the owner and/or operator of products or facilities generally produced by the private sector under contract to the government. These include the DOE, NASA, and the USN part of the shipbuilding industry. The second subcategory is characterized by those instances of private sector endeavors being regulated by a government agency. Aircraft manufacturing and commercial shipbuilding are examples of this subcategory. Foreign nuclear programs reviewed include both government and private ownership and operation of nuclear power plants.

The following domestic programs were studied:

- the Federal Aviation Administration (FAA) program as applied to the manufacture of large commercial transport aircraft
- the Department of Energy (DOE) program as applied to a government-owned nuclear reactor project, the Fast Flux Test Facility, and a nuclear project for enrichment of uranium, the Gas Centrifuge Enrichment Program
- the National Aeronautics and Space Administration (NASA) program as applied to the aerospace industry
- the U.S. Navy (USN) program for shipbuilding under the Department of Defense
- the Maritime Administration (MarAd) program for commercial shipbuilding under the Department of Transportation.

The programs have been studied to the extent that each can be characterized with respect to its AOQ features and activities and to identify specific elements that may have potential application to the NRC program. Each program was studied in sufficient depth to gain a good understanding of the total program to adequately analyze those particular features deemed pertinent to the NRC program. No attempt was made to evaluate the effectiveness of these outside programs.

Each program was studied by reviewing the publicly available information describing the program, including legislation, regulations, guides and miscellaneous instructions. The literature review was supplemented by interviews with representatives from the government agencies and by interviews with pertinent private sector representatives involved in the DOE, FAA and NRC endeavors. There were also limited contacts with NASA representatives. The characterizations of the USN, MarAd, and foreign nuclear programs are based entirely upon literature reviews, except for limited discussions between subcontractors and a few people in the foreign countries. In the case of the USN and MarAd programs, an experienced, expert consultant assisted in developing the program characterizations.

The studies of the foreign nuclear regulatory programs were conducted primarily by subcontractors selected on the basis of their already existing knowledge of the programs, their geographical locations, and their ability to overcome language differences. The programs in West Germany, France and Sweden were studied by Battelle Institute e.V. located in Frankfurt, Germany. The programs in the United Kingdom, Japan and Canada were investigated by the NUS Corporation, including their Japanese subsidiary, JANUS. Assistance in studying the programs in Sweden and Japan was provided by N. C. Kist and Associates.

The reviews of the foreign nuclear programs were based almost entirely upon publicly available information. These reviews were supplemented with subcontractor knowledge of these programs. Because the information obtained in this way is limited, it may be desirable that some of the foreign nuclear programs be selected for a more in-depth study at a later date.

It was also important to characterize the NRC program for assuring quality in design and construction of nuclear power plants, in order to properly consider adopting features from other programs. The abundant literature available on the NRC program was reviewed and supplemented with interviews of officials in the NRC's Inspection and Enforcement Office and with interviews of staff in regional offices for Regions 2, 4 and 5.

D.2 CONCLUSIONS AND FINDINGS

There are several significant differences among the programs investigated in this study:

- the nature and extent of the interfaces between the government sector and the private sector differ
- the incentive systems for achieving quality vary
- in some cases, the major thrust for quality needs arises from safety considerations; in others, from a need for reliable performance; however, safety and reliability are frequently closely intermixed.

Each of the programs reviewed in this appendix operates within its own "cultural ambience" and such differences profoundly affect the resulting program for assuring quality. This is particularly evident in the foreign nuclear programs.

In spite of such differences, there are also identifiable areas of commonality. One example is that all of the programs studied are quite dynamic. Although each of the programs has experienced its own evolutionary process and some are much older than others, changes aimed at improving the effectiveness of the QA programs are ongoing.

One of the observations from this study is that the FAA, NASA, USN, and MarAd shipbuilding regulatory programs are directed towards industries that have evolved as specific entities. These are, respectively, the aircraft manufacturing industry, the aerospace industry, and the shipbuilding industry. Each of these industrial sectors obtains equipment, materials and services from other industrial sectors. Design and fabrication are normally performed by industrial sectors that have evolved generally in parallel with the corresponding regulatory programs. In contrast, the NRC program is directed towards regulating the "nuclear industry," which has never evolved as a specific industrial entity in the traditional sense. The design and construction of nuclear power plants is accomplished as an offshoot activity from several traditionally established industries, each with its own historical methods of doing business. These are the electrical utilities, the architect-engineers, the major power plant equipment suppliers, and the construction industry. Implementing the NRC program in these industries has required major changes in traditional practices. Furthermore, the NRC program is directly applied to each utility that chooses to build a nuclear power plant with the stipulation that the requirements be passed on to others.

One consequence of the complex institutional arrangement for building nuclear power plants has been that major changes in long-established ways of doing business have been imposed across a large number of business-management interfaces. It is beyond the scope of this study to pursue such a complex issue to the point of developing recommendations; however, it is reported here as an issue that emerged from the study of other programs and is deserving of further study.

Although significant differences exist between the NRC's AOQ program and the other programs reviewed, some elements of the other programs may be applicable to the NRC program.

The major findings discussed in this appendix were derived from studies of the various individual programs. It must be emphasized that these studies were limited in scope to general concepts. Therefore, these findings should be viewed as features worthy of consideration by the NRC for its assurance of quality program rather than as features that should be immediately adopted.

In formulating these findings, consideration was given to the institutional differences that exist between the NRC and between the outside programs reviewed. For example, the relationship between the government and the private sector is of a regulatory nature in some cases (FAA, NRC, MarAd) and a contractual nature in others (DOE, NASA, USN). Other intrinsic aspects of the programs studied include cultural differences, as observed in the foreign nuclear programs, and a national commitment to developing the product, as observed in the USN shipbuilding, NASA, and foreign nuclear programs.

Findings are categorized below by Design, Assurance of Quality Programs, Program Reviews, Vendors, Inspection Programs and Craftsmanship.

D.2.1 Design

The NRC should consider requiring that plant designs be well advanced prior to initiating construction activities. Design requirements should include the completion of safety, reliability, and availability analyses including failure mode and effect analyses, and fault-tree and hazard analyses. The analyses should be integrated with QA and should be completed prior to the initiation of construction. This recommendation is based upon findings from the DOE, NASA, FAA, foreign nuclear, and shipbuilding programs.

D.2.2 Assurance of Quality Programs

The NRC should consider establishing a QA system that prioritizes levels of quality efforts. Systems and components should be assigned to the various priority grades on the basis of the safety, reliability and availability analyses discussed under "Design" above. This recommendation is based upon findings from the DOE, NASA, and shipbuilding programs.

D.2.3 Program Reviews

The NRC should consider adopting the following three recommendations, which relate to program reviews:

1. The NRC program should require "readiness reviews" during nuclear power plant construction. These reviews might involve plant designers, construction managers, owner-operators, and (possibly) NRC staff and should be required at key points in the project beginning with "design ready for construction." It may be useful to have additional reviews at selected key milestone points. This recommendation is based upon findings from the DOE, NASA, and shipbuilding programs.

2. The NRC should study ways to better integrate NRC inspection functions with system design reviews, test program reviews and test program evaluations. This recommendation is based upon findings from the USN, FAA, DOE, and NASA programs.

D.2.4 Vendors

Consideration should be given to expanding the NRC's vendor inspection program. The licensee should continue to be held fully responsible for vendor-supplied items. Necessary enforcement actions relevant to vendors could be applied to the licensee. The NRC should consider supporting, perhaps through the Institute of Nuclear Power Operations (INPO), continued development of a data bank on performance of and problems with vendor-supplied components. These data should be analyzed and the results published periodically. This recommendation is based upon findings from the FAA, USN, and foreign nuclear programs.

D.2.5 Inspection Programs

The NRC should consider adopting the following inspection-related points:

1. The NRC should expand its inspector training program to increase the emphasis on "how to inspect." Such a program should concentrate on such areas as conducting inspections, use of time, and interpersonal skills and should include specific guidance on identifying possible indicators of developing problems. This recommendation is based upon findings from the USN program.

2. The NRC should consider requiring inspections of nuclear power plants by independent inspecting agencies. This recommendation is based upon findings from the foreign nuclear programs.

D.2.6 Other

The NRC should re-examine its posture on assurance of quality to emphasize to the licensees that quality and the assurance of quality are responsibilities of overall management rather than responsibilities of the QA/QC organizations. This recommendation is based upon findings from the DOE program.

D.3 SIGNIFICANT FINDINGS FROM EACH PROGRAM

The intent of this study was not to evaluate the other programs studied but, rather, to focus on identifying features with potential for improving the NRC program. In general, these were features that were viewed as positive factors in their respective programs by the administrators of those programs. This section discusses the significant findings from each of the programs to provide a basis for the major findings presented in Section D.2.

D.3.1 FAA Program

The portion of the FAA program that was reviewed is that relating directly to the design and manufacture of large, commercial transport aircraft. The following five items are considered to be significant findings from this program relative to the NRC program.

1. The FAA closely reviews and monitors all of the design, fabrication and flight testing of prototype airplanes. This involvement includes flight tests by FAA pilots. It is only after these flight tests of prototypes that the first FAA certificate, Type Certificate, is issued for a new aircraft model. Both designated engineering representatives and designated manufacturing and inspection representatives are utilized extensively throughout this process to supplement the FAA's resources. These representatives are industry employees, individually certified by the FAA to conduct certain review and inspection activities on behalf of the government. This practice reflects the very substantial FAA effort in this phase of producing a new airplane.

2. The FAA reviews and approves all of the manufacturer's QA/QC, work performance, and testing procedures prior to issuing a Production Certificate. This permits the manufacturer to produce replicated aircraft following the FAA issuance of a Type Certificate for that model.

3. The aircraft manufacturer is held responsible for safety and quality but the FAA accepts some responsibility for the certification program being properly conducted.

4. The FAA issues certificates to vendors supplying parts for airplanes but holds the prime manufacturer responsible during the manufacturing process, including enforcement actions being applied to the prime

manufacturer rather than to the vendor. After airplanes are in service, the vendor certification program is of greater significance and the FAA interfaces more directly with the vendors. When supplied parts cannot be fully inspected after delivery, more attention is devoted to the vendor's plant.

5. Although it is not required by the FAA, aircraft industry practice requires that mechanics sign off completed work prior to QC inspection. Some items are also signed off as acceptable by FAA inspectors or the designated representatives.

D.3.2 DOE Program

Two DOE projects were studied. One is the Fast Flux Test Facility (FFTF) at Hanford, Washington. Operated under the control of the Richland Operations Office of DOE, the FFTF was constructed in the 1970s. The basic element of this facility is a fast reactor that achieved operational testing in 1980. The other project is the Gas Centrifuge Enrichment Program (GCEP), which is currently under construction near Portsmouth, Ohio, under control of the Oak Ridge Operations Office. The significant findings from these projects are as follows.

1. Both projects used a prioritized quality assurance program. At the FFTF three and later four levels of quality assurance were established. At GCEP two basic classifications used are "routine" and "special." A relatively standard QA program is applied to routine items and specific quality assurance action plans are prepared for special items which may incorporate additional variations, depending upon the established degree of importance.

2. Thorough design reviews were conducted on both projects. In both cases steps were taken to assure that all potentially impacted interests were represented in the design review process.

3. At GCEP the QA efforts are combined with a specific systems engineering effort early in the design process. This includes the use of failure and effects modes analyses and reliability, availability, and maintainability analyses. The developed listings of critical items from these analyses provide a basis for determining the extent of the graded QA/QC to be applied.

4. Both projects have used a form of "readiness reviews" prior to initiating the next or new project phases or activities. In both projects, care has been taken to include the plant owner, engineering design, construction management, and operations interests in these reviews.

5. Both projects have emphasized that quality is a line management responsibility rather than the responsibility of the quality assurance organization. In other words, there has been a major effort to integrate quality assurance into the overall management process of both projects.

D.3.3 NASA Program

To date the study of the NASA program has been primarily limited to a review of the available literature. Based upon this limited review, however, the following findings have been identified as significant.

1. NASA applies an extensive "systems approach" to safety and reliability considerations. This incorporates, for example, risk-of-failure analysis, failure modes and effects analysis, single-failure-point analysis, criticality analysis and hazards analysis, using systems engineering techniques to identify the critical items for application of more stringent QA/QC controls. This systems approach is initiated early in the design phase and is ongoing throughout a project.

2. NASA requires that detailed designs be essentially completed prior to starting fabrication.

3. NASA's contractors are required to establish appropriate QA/QC programs and these programs are closely monitored by NASA.

4. NASA uses detailed, in-depth readiness reviews at predetermined stages of the project. Among other things, these reviews verify that any and all changes and discrepancies have been properly addressed and dealt with.

D.3.4 Shipbuilding Program

The study of the shipbuilding industries was based entirely upon review of publicly available information. The USN programs studied involved the design and construction of both nuclear and nonnuclear ships. In this instance, the USN is the owner, the operator, and the regulator.

In the case of the MarAd programs, the ships are designed, built and operated by private organizations. However, there is extensive financial participation by the federal government in constructing these ships. Consequently, a single government agency, the Department of Transportation, simultaneously promotes and regulates the design and construction of the vessels. The significant findings from both the shipbuilding programs are as follows.

1. A close and cooperative relationship has developed, apparently successfully, between the builders, buyers, regulators and standards-setting organizations.

2. In both the USN and the MarAd programs, the fabricating contractor is held responsible for the assurance of quality, with a significant inspection overview effort by USN inspectors for Naval vessels, and by U.S. Coast Guard inspectors for Maritime ships.

3. Designs for ships are reviewed and approved by the responsible federal agency before construction begins. For the Maritime ships,

design reviews by the American Bureau of Shipping may be accepted or supplemented by U.S. Coast Guard reviews.

4. Design and fabrication is performed by a relatively small number of shipyards with a work force considerably more stable than in the general construction industries.

5. The standardization of ship design is a major policy of the Maritime industry and the USN.

6. The USN uses a graded QA system to identify critical equipment, systems and/or material.

7. The USN provides specific guidance for its personnel and its contractors to prevent or detect deliberate malpractice and fraud.

8. The USN has developed a data bank for analyzing the performance of vendor-supplied components.

.3.5 NRC Program

The NRC program for assuring quality in the design and construction of nuclear power plants was not studied in great depth. The objective was to investigate the NRC program sufficiently to have a good understanding of the program as a basis for considering specific features identified in the other programs. This understanding is important in determining those features that deserve further investigation for potential adoption by the NRC. This less-than-in-depth study did, however, identify the following findings considered to be significant when considering the applicability of findings from the other programs to the NRC program.

1. The NRC holds the licensee (the utility) totally responsible for quality and safety in the design and construction of nuclear power plants.

2. The "nuclear industry" does not exist in the United States as a specific entity in the traditional sense. Therefore, the regulation of this industry has been more difficult because it has required bringing about significant major changes in traditional methods and practices of several industries that continued to perform other types of work. These include the utilities, the architect-engineers, the equipment suppliers, and the constructors. The regulatory process is therefore applied to offshoots of several established industries by focusing on one of them (the utilities) and requiring that the regulations be passed on to the others (i.e., the vendors, contractors and suppliers).

D.3.6 Nuclear Regulatory Programs in Other Countries

This section identifies the findings considered significant from the studies of the AOQ programs for building nuclear power plants in six other countries. These findings are identified below by the country of interest.

Canada

The significant findings of a study of the AOQ regulatory program in Canada are as follows.

1. A graded approach is used with five levels. The level is determined based upon an evaluation of six factors (design complexity, design maturity, manufacturing complexity, item or service characteristics, safety, and economics).

2. The regulatory process is a joint effort between national and provincial governments which relies on technical expertise of the utility, except for critical pressure components.

3. The emphasis in design and construction is in establishing quality engineering rather than documentation of existing practices. The term "quality engineering" refers to the management decision process which ensures that all parties involved communicate with each other and clearly understand requirements and objectives throughout the design and construction process.

4. Suppliers are qualified by the utility before a contract award, and the Canadian Standard Association has initiated a qualification program.

Federal Republic of Germany

The significant findings from a study of the assurance of quality regulatory program in West Germany are as follows:

1. The regulatory process, including the setting of rules, is conducted in more of a collaborative mode than an adversarial mode between government and industry.

2. The utilities in West Germany contract with a single organization for the total design and construction of a nuclear power plant on a turn-key basis. The contractor therefore bears full vendor's liability.

3. The onsite inspection functions to assure compliance with regulatory requirements are performed by independent, not-for-profit organizations, Technische Uberwachungs-Vereine (TUVs). These are organizations which have a long history of providing inspection services in a number of business and industrial areas, and they are accepted as highly competent and trustworthy.

4. The control measures and inspections are predominantly hardware- or product-oriented. "Supplier Certificates" and "N" stamps are not used, but the suppliers of equipment and plants must show to the inspection authority's satisfaction that standards are met.

5. In addition to a safety report, the applicant for a license (the utility) must provide "factual statements enabling the examination of the reliability and expert knowledge of the persons responsible for the erection of the installation and the management and control of its operation as well as factual statements enabling the examination of the requisite knowledge of all persons working on the installation." (From the License Procedure Ordinance, "AVerfVO.")

France

The signifcant findings from the study of the assurance of quality regulatory program in France are as follows:

1. The light water reactor power plants in France are designed and constructed under a turnkey arrangement with Framatome, a government-owned corporation that designs the plants, manages the construction and provides the nuclear steam supply system for the utility, which is also government-owned.

2. A series of three standardized nuclear power plant designs have been licensed. Additional licensing considerations for each plant are restricted to consideration of siting issues.

3. The onsite inspection activities on behalf of the government are by private individuals or small associations. These inspectors have not only been qualified by the government and certified, but individually take an oath of office and therefore function as government deputies.

4. The single utility, which operates all of the light water reactor plants, has developed a sophisticated information system to gather data on operating experience. These data are used as a basis for improvements in plant designs and components.

Japan

The significant findings from the study of the assurance of quality regulatory program in Japan are as follows:

1. The government agency, Ministry of International Trade and Industry (MITI), and licensees have a mutual trust and cooperation based upon a stated common goal of safe operations. MITI has also licensed an independent nonprofit organization, the Japan Power Plant Inspection Institute (JPPII), which is

funded by users to perform inspections of welds and hardware. When JPPII performs an inspection, no additional inspection is performed by MITI. MITI inspections are primarily programmatic.

2. The QA practices emphasize the inspections and records rather than the system. Certain inspections are required by law.

3. The current system does not include regulatory criteria for QA, but the Japan Electric Association has published QA guidelines. MITI established a QA Investigation Committee in 1980, which recommended a QA program similar to those in the U.S. (10 CFR 50 Appendix B) and Europe.

4. ASME Stamp Accreditation has been used in Japan since 1973. MITI established a Committee for Nuclear Accreditation under the JPPII which is an agency authorized to inspect nuclear power plant components on behalf of MITI. The Committee has discussed the introduction of an accreditation system similar to ASME "N" stamps and establishment of a third-party agency to conduct surveys and audits.

Sweden

The significant findings from the study of the assurance of quality regulatory program in Sweden are as follows:

1. The program for constructing nuclear power plants in Sweden has taken advantage of replicated basic designs.

2. The government regulatory agencies have relatively small staffs and rely heavily upon reviews and inspections performed by a nonprofit, government-owned, third-party organization. This organization reviews designs, inspection plans and work procedures, and inspects hardware.

3. A "hold point" system is utilized by the independent inspection agency at specific points in the construction program. The third party must approve designs, inspection plans and work plans and procedures before construction is allowed to proceed with specific activities.

United Kingdom

The significant findings of a study of the assurance of quality regulatory program in the United Kingdom are as follows:

1. A "hierarchical system" is used in which the extent of responsibility and authority, and the lines of communication, are clearly defined starting from the licensee through the main contractor and finally to the smallest supplier. Although any higher-order organization may

audit QA/QC practices of any lower organization, an organization is only accountable to the organization immediately above it in the hierarchy.

2. The site license is granted only after design intent and safety principles and the construction design description are judged sufficiently complete that construction can proceed with small risk of significant changes being subsequently required for safety reasons.

3. QA/QC procedures approval by the Nuclear Installations Inspectorate (NII) is a license condition.

4. Inspection and testing of major items may be carried out by the licensee's own inspection organization or by recognized independent inspecting agencies, but the arrangement requires NII approval.

5. NII inspectors visit each site to witness tests and examine test records, and NII consents are required at various major steps bebore construction proceeds further.

6. There are four grades of QA requirements normally employed, namely: "Q" - highest grade for safety class plant items; "N/S" - important to safety and "N/O" - important to operational reliability items; "N/E" - lower class items which still require significant design engineering; and "N/-" - the lowest class of off-shelf, mass-produced items.

D.4 SUMMARY OF ASSURANCE OF QUALITY (AOQ) PROGRAMS

This section provides a brief summary of each of the AOQ programs studies that resulted in the findings identified in Section D.3. Time restraints precluded the NRC staff from forwarding the summary descriptions to all the government agencies for their review, comment, and correction. As a result, inaccuracies may exist in these summaries. If warranted, corrections to these summaries will be made in future revisions or supplements to this report.

D.4.1 FAA Assurance of Quality (AOQ) PROGRAM

This part of the study focused on the Federal Aviation Administration's (FAA) program for assuring quality in the design and manufacture of large commercial transport aircraft. To obtain program information, publicly available documents on this program were reviewed. FAA staff in Washington, D.C., and staff in the Transport Airplane Certification Directorate Office, Seattle, Washington, also were interviewed. Staff of the Boeing Co. also were interviewed, including a Designated Engineering Representative (DER) and a Designated Manufacturing Inspection Representative (DMIR). Finally, limited observations of aircraft manufacturing work in progress were conducted at Boeing.

The Assurance of quality (AOQ) program being applied to the licensing and certification of large commercial aircraft is all-inclusive in that it addresses all aspects of design, material fabrication, assembly and tests.

Like nuclear reactors, aircraft involve highly complex technology and require high-quality standards in their design, construction and operation.

Aircraft are complex structures that are fabricated of many lightweight systems located in limited space. The aircraft must perform in a wide variety of environments for many years. Aircraft safety demands not only a design that is tolerant of failure, but also careful production that is of the highest quality and excellent maintenance following manufacturing.

The Federal Aviation Act of 1958 authorizes the FAA to issue certificates for aircraft in the interest of safety. Section 603.A of the Act addresses the requirements for a "Type Certificate" (design). The requirements for a "Production Certificate" (production) are covered in Section 603.B, while Section 603.C states the general requirements for an "Airworthiness Certificate" (license for operation). Essentially, these sections of the Act address the safety of or the assurance of quality for the aircraft.

D.4.1.1 Organization and Responsibilities

The responsibilities for an airworhtiness program in the FAA involve both headquarters and field operations. Headquarters is responsible for establishing rules, issuing directives, and distributing guidance publications. Field operations are responsible for the receipt of applications, examination, certification, surveillance, and enforcement.

Title VI of the Federal Aviation Act sets forth the responsibilities of the basic certification processes. The interested party files an application, and the FAA makes a finding and issues certificates as well as any regulatory corrective action necessary. The FAA is also responsible for certificate amendment, suspension, and revocation. The administrator is given the responsibility to issue minimum standards, rules, and regulations as well as the use of various kinds of airworthiness inspectors. The responsibilities and duties of the industry require "air carriers to perform their services with highest possible degree of safety in the public interest."

Policy and guidance responsibilities are retained at FAA headquarters, while the field offices develop and implement programs. Airworthiness programs are carried out by four regional directorates located in Seattle, Washington (commercial transport aircraft); Ft. Worth, Texas (rotary aircraft); Kansas City, Kansas (general aircraft); and Boston, Massachusetts (engines and propellers). The Seattle office has responsibility for review and oversight of commercial transport aircraft design, production, determination of airworthiness, and maintenance throughout the world.

The directorates were established to perform technical policy and airworthiness project management for the aircraft certification programs. The directorates of the regional offices report to the Administrator. The directorates, while assigned specific policy and programmatic responsibilities, are also responsible for implementation of the airworthiness programs within their respective geographical boundaries.

D.4.1.2 Certification Program

In issuing certificates for aircraft, the FAA is responsible for exercising its powers and performing its duties to reduce or eliminate the possibility of accidents in air transportation. This section discusses the three certification programs employed by the FAA to assure the quality of large commercial transport aircraft: the Type Certificate, the Production Certificate and the Airworthiness Certificate.

Type Certificate. The first step in the FAA's certification of an aircraft is design approval or Type Certification. The Type Certificate is an FAA approval of an aircraft design based on engineering review of reports, drawings, and data, and on flight tests and tests of materials and parts. The FAA review during the Type Certificate process is very detailed and includes a design review of basically all parts and pieces of the aircraft. The Designated Engineering Representative (DER) activities are a very integral part of this FAA review process. Designated Manufacturing Inspection Representatives (DMIR) also provide support in the Type Certification program during the production of prototype aircraft or parts for testing. The DMIR provides conformity inspection assistance to the FAA during the long proto-typing process which precedes the Type Certificate.

Type Certificates are issued for complete aircraft, but they may also be issued for components such as engines and propellers. Basically, the FAA defines the minimum safety standards to be met, and the applicant develops, defines, analyzes, tests and shows compliance with the requirements to obtain design approval. Before a Type Certificate is issued, the FAA evaluates the applicant's compliance by design review, inspection of prototype fabrication, and performance of flight tests.

All of the activities leading to a Type Certificate are monitored closely by the FAA. The FAA has prepared and issued a handbook (Order 8110.4 Type Certification) to guide and assist all personnel in performing their responsibilities and in efficiently accomplishing the assigned tasks.

Production Certificate. After the conditions of the Type Certification program have been met, the Production Certification phase begins. To obtain a Production Certificate, the the manufacturing facility and process for the replication of a Type Certificated aircraft, including the manufacturing quality control system, must be approved by the FAA. In issuing the Production Certificate, the Administrator can inspect and require any tests of the aircraft, aircraft engine, propeller, or appliance as is needed to assure that each unit has been manufactured adequately according to program specifications. If the Administrator approves production duplicates of the aircraft, aircraft engine, propeller, or appliance for which a Type Certificate has been issued, then a Production Certificate is issued, authorizing the production of such duplicates. In the Production Certificate program, the Administrator may set the duration of the certificate and any other terms, conditions, and limitations required in the interest of safety.

Assuring the adequacy of the production system involves various levels of FAA quality control surveillance. FAA inspectors review and approve the company's manufacturing, QA/QC and testing procedures and processes.

Before the Production Certificate is issued, the FAA requires applicants to demonstrate that a QA system will be established and maintained so that each plane produced will meet the design provisions of the applicable Type Certificate. Each applicant for a Production Certificate must also submit to FAA for approval the following information:

- a statement of QA organization and responsibilities
- a description of inspection procedures for materials, parts, and supplies
- a description of the methods used for production inspection
- an outline of the materials' review system
- an outline of the system for informing QA inspectors of manufacturing changes
- a chart showing the location of inspection stations
- information on delegation of inspection authority to subsidiary manufacturers.

A holder of a Production Certificate must allow the FAA to make any inspections it desires (including suppliers) to assure compliance with the above requirements.

The FAA has considerable involvement in and control over a manufacturer's processes through the requirements of Production Certificates. Also, the FAA exercises a similar control over various suppliers and vendors who are considered an extension of the manufacturer or prime contractor. However, most enforcement actions resulting from problems associated with vendors or suppliers are applied to or through the prime manufacturer of the aircraft. FAA involvement occurs primarily through the manufacturer, the holders of a Type or Production Certificate, through Parts Manufacturer's Approval (PMA), or through a Technical Standard Order Authorization (TSOA). When parts supplied to a manufacturer cannot be adequately inspected after delivery, the FAA may inspect them at the supplier's location.

The PMA and TSOA are used primarily when parts are supplied for repair or modifying aircraft in service. In both cases, the FAA issues an approval (license) for the manufacture of certain parts to an approved design after FAA approval of the process and the QA/QC program and procedures. These approvals give the FAA the prerogative to inspect and audit the facilities, products, and processes of a manufacturer and his suppliers.

Order 8120.2A, Production Approval and Surveillance Procedures, was prepared to guide personnel in accomplishing FAA's responsibilities for the evaluation, approval, and surveillance of the production activities of manufacturers and their suppliers producing products, parts and appliances in accordance with Code of Federal Regulations 14 CFR, Part 21.

Airworthiness Certificate. The third and major part of FAA's certification of an aircraft is the original Airworthiness Certification program. An

Airworthiness Certificate from the FAA is required for a U.S. registered aircraft to operate. Basically, the registered owner of any aircraft may file an application for an Airworthiness Certificate with the Administrator. The Airworthiness Certificate is issued after the Administrator finds that the aircraft conforms to the Type Certificate, and if that aircraft is found to be in condition for safe operation after inspection. The Administrator can set the duration of the certificate, the type of service for which the aircraft may be used, and any other terms, conditions, and limitations that are required in the interest of safety. Each certificate is registered by the Administrator and can include any information that the Administrator feels is necessary.

The FAA has issued Order 8130.2B, entitled Airworthiness Certification of Aircraft and Related Approvals, which contains procedures and instructions for personnel involved in issuing Airworthiness Certificates and related approvals.

D.4.1.3 Program Implementation: Designated Representatives (DR)

To ensure that the design and fabrication of a new airplane meets all regulatory requirements, the FAA is assisted by specified independent persons who also may be employees of the aircraft manufacturers. In accordance with the Civil Aeronautics Act of 1938, examinations and reports could be accepted from properly qualified private persons in place of those made by government employees. In 1950, Congress passed bills authorizing the delegation of certain functions to properly qualified private persons (designated representatives). These functions include the examination, inspection, and testing necessary for issuing certificates in accordance with properly established standards.

These Designated Representatives (DR) review the design and fabrication processes to ensure compliance with all aspects of the regulations. In 14 CFR, Part 183, Representatives of the Administrator, the requirements are described for designating private persons to act as representatives of the Administrator in examining, inspecting, and testing persons and aircraft prior to the issuing of airman and aircraft certificates. In addition, it states the privileges of those representatives and prescribes rules for exercising those privileges. The review of the Designated Representatives program focused on the following two types:

- Designated Engineering Representative (DER). Individuals designated to approve engineering information. Order 8110.37, DER Guidance Handbook, identifies the policies, procedures, technical guidelines, and limitations of authority for DERs. This information is amplified in Chapter 5 of Order 8110.4, Type Certification.

- Designated Manufacturing and Inspection Representative (DMIR). Individuals designated to issue original airworthiness, export, ferry, and experimental certificates. The qualifications, appointment, responsibility, authority, etc. of DMIRs are identified in Chapter 8 of Order 8130.2B, Airworthiness Certification of Aircraft and Related Approvals.

The DER principally supports the FAA in issuing Type Certificates. The DMIR principally supports the FAA in issuing Airworthiness Certificates, and, when necessary, the DMIR provides support for a Type Certificate during the production of prototype aircraft or parts for testing.

The DER and DMIR are authorized to perform certain examinations, inspections, and tests on behalf of the FAA. Depending on the specific limitations in their designation, they also provide FAA approval (sign-off) or recommend approval by the FAA. DER activities focus on insuring compliance with the requirements of the FAA regulations, whereas the DMIR principally ensures that aircraft and components are manufactured according to FAA-approved designs, specifications, and QC programs.

Designees are usually nominated by the applicant (aircraft manufacturer) and are appointed by the FAA regional director after the director reviews their personal and professional qualifications and experience. Once appointed, they are delegated by the FAA Administrator, through the regional office, to represent the FAA in helping to determine that the aircraft complies with the relevant requirements of the regulations. In this capacity, designees are bound by the "...same requirements, instructions, procedures, and interpretations as FAA employees..." (FAA 1967). While designees perform considerable work for the FAA, the agency reserves for itself the approval of the following necessary elements in the certification process:

- the regulatory process
- analytical criteria to be used
- major design philosophy affecting safety
- all fault-type safety analyses
- all test proposals
- witnessing of all major tests
- all major flight testing
- all in-service safety problems
- aircraft flight manual
- QC manual
- surveillance of production facilities
- production certification of facilities and QC functions.

D.4.1.4 Industry's QA Program

As part of this study of FAA quality assurance programs, staff at one plant were interviewed and work was observed. Each of the QA functions that constitutes the foundation of the QA/QC system in the manufacture of large commercial transports is briefly described in Table D.1 (FAA 1976).

In reviewing the industry program it was noted that fabrication is tracked by a very detailed operations and inspection record. After a particular item of work has been completed, the record is initialed or stamped by the person performing the activity. Then, inspections are performed by company employees who are required to verify by formal record that the product meets the established standards. This record signifies who performed each task and that the inspector stands behind the proper performance of the work. Also, articles are tagged or stamped with marks that identify the individual inspector and ensure that only inspected and accepted items are used in the finished product. For

TABLE D.1. Descriptions of Quality Assurance Functions (FAA 1976)

1. TECHNICAL DATA CONTROL--Assures that only the latest approved drawings, drawing change notices, engineering data, etc. are available to production and inspection personnel and that obsolete drawings and data are promptly removed from the production and inspection areas.

2. MANUFACTURING PROCESSES--Provides for selecting and controlling procedures to ensure that all characteristics affecting safety will be inspected and that products or processes conform to approved design data where specific operations such as machining, riveting, welding, etc. are performed.

3. SPECIAL PROCESSES--Controls all processes and services such as welding, heat treatment, bonding, plating, casting, forging, etc. where the material being processed undergoes any physical, chemical, or metallurgical transformation and the conformance to specifications cannot be verified by external visual inspection.

4. INSPECTION/IDENTIFICATION--Ensures that only articles and processes that have been accepted and that conform to approved design data are used in the product. Items are identified with stamps or marks traceable to qualified individuals.

5. NONDESTRUCTIVE INSPECTION--Establishes requirements for inspection methods used to determine conformity to the design data through or by a means which will not have a detrimental effect on a part. Example: Magnetic particle, ultrasonic radiographic, etc.

6. TOOL AND GAUGE CONTROL--Establishes control of precision weight and measuring devices (tools, scales, gauges, fixtures, etc.) used in fabricating and inspecting parts, assemblies, and complete products to assure conformity to type design data.

7. SUPPLIER CONTROL--Encompasses the purchasing, testing, and acceptance of all materials, parts, and services furnished the manufacturer from an outside source, including proprietary items.

8. TESTING--Assures that all functional components and/or assemblies are subjected to tests that will ensure that the product will perform its intended function safely.

9. MATERIALS REVIEW--Identifies system of control for withholding, evaluating and disposing of all materials, parts, etc. that do not conform to engineering design data.

10. STORAGE AND ISSUANCE--Assures proper protection and prevention of damage and deterioration of materials, parts, assemblies, etc. that have passed inspection while awaiting use. Also assures that only articles current with applicable design changes are released for incorporation in the product.

TABLE D.1. (contd)

11. AIRWORTHINESS CERTIFICATION--Identifies system for evaluation of the completed article or product and related documents to assure that all required inspections and tests have been satisfactorily performed and that it is in a condition for safe operation.

12. SERVICE DIFFICULTIES--Establishes a system for recording, investigating, determining cause, and assuring corrective action on all known or reported failures, malfunctions, or defects.

example, suitable "acceptable," "rework," or "rejection" stamps are placed on articles subjected to heat treatment, welding, riveting, soldering, hardness tests, laboratory analysis, and other tests. It should be noted that the sign-off of completed work by the mechanic who did the work is not required by the FAA, but is reportedly an aircraft industry practice.

D.4.2 Department of Energy (DOE) Assurance of Quality (AOQ) Program

The DOE, its predecessor organizations Energy Research and Development Administration (ERDA) and the Atomic Energy Commission (AEC), and contractor organizations and laboratories have been developing, constructing, and operating nuclear reactors and other nuclear facilities for some four decades. They have developed and applied many methods and practices for safely carrying out these activities. Many of the accepted and proven practices of nuclear technology, such as the nuclear application of QA and engineering standards, were pioneered in these endeavors. For this reason, two DOE nuclear projects were selected for review in this study to determine whether there were attributes of the DOE Program for assurance of quality which may be transferable to the NRC. The first DOE project reviewed, the Fast Flux Test Facility (FFTF), is a reactor facility that achieved initial start-up in 1980. The other one, the Gas Centrifuge Enrichment Plant (GCEP) for uranium enrichment, is currently under construction. The assurance of quality program for each project is discussed separately in Sections D.4.2.2 and D.4.2.3. The following section gives a brief overview of the DOE organization and responsibilities for nuclear programs.

D.4.2.1 Background

The Atomic Energy Commission was disbanded by the Energy Reorganization Act of 1974 and replaced by NRC and ERDA. Section 107(a) of the Energy Reorganization Act states that the nuclear functions of ERDA will be subject to the Atomic Energy Act of 1954. All functions of ERDA were transferred in 1977 to DOE by the DOE Organization Act. DOE is basically subject to the same directives regarding safety and AOQ in the Atomic Energy Act as the NRC.

The Atomic Energy Act has no specific language addressing AOQ. Indirectly, however, the act empowers DOE to regulate AOQ to protect health and safety and to minimize danger to life and property. A basic purpose of the Atomic Energy Act is to encourage widespread use of atomic energy, but only to the extent that its use is consistent with the health and safety of the public. Section 161(b) of the Atomic Energy Act requires DOE as follows:

> Establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and by-product material as may be deemed necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property.

DOE was formed in 1977 to centralize responsibility for national energy policy and to continue and expand the energy research and development that was transferred from the Energy and Research Development Administration (ERDA). The DOE Organization Act of 1977 placed the operation of government-owned nuclear plants and the independent safety overview function in a larger organization. Normally, these programs were administered through an agency headquarters group, and facilities were operated by a contractor at the site. A DOE field office, located on or near the site, provides close oversight of the programs.

The organizational placement of nuclear energy activities in DOE can be characterized as decentralized. Although essentially all duties of the Assistant Secretary for Nuclear Energy are nuclear related, other major nuclear activities have been assigned to the Assistant Secretaries for Defense Programs; Environment Protection, Safety, and Emergency Preparedness; International Affairs; and to the Director of Energy Research.

The management of the DOE nuclear programs (including the FFTF and GCEP is generally administered through three organizational tiers depicted in Figure D.1.

The DOE field organization and project officers have overall responsibility and authority for defining and assuring effective implementation of required quality assurance (QA) activities to be established and implemented on DOE programs by contractors under their direction. Any order or standard that DOE adopts can readily be made applicable to the activities of its contractors simply by inserting an appropriate applicability clause in the contract.

D.4.2.2 Fast Flux Test Facility

In addition to reviewing pertinent project documents for the DOE's FFTF, interviews were conducted with DOE headquarters staff in Germantown, Maryland, and in the Richland Operations Office (RL), Richland, Washington. Staff at the Westinghouse Hanford Corporation (WHC), which operates the facility, were also interviewed.

Background. The FFTF is a 400 MW (thermal) sodium-cooled fast neutron flux reactor designed for the irradiation testing of fuels, materials and components for fast breeder reactors.

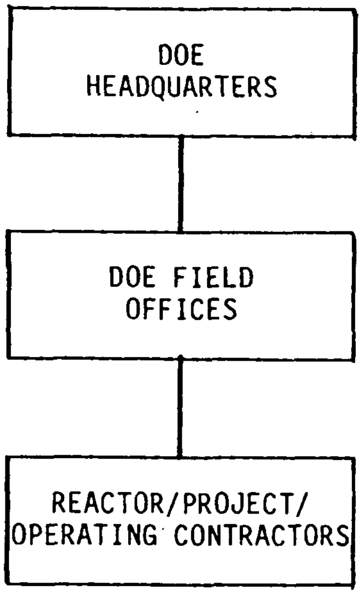

FIGURE D.1. Organizational Tiers in Nuclear Field Programs

In the FFTF, fuels and materials are exposed to conditions typical of those expected in future reactors and, in some cases, to conditions beyond anticipated plant conditions to explore safety margins, to extend fuel technology and to build confidence in the design of future power plants. The FFTF was initially started up in 1980 and recently completed the third of its planned cycles of operation. Performance to date has exceeded DOE's expectations and program milestones.

The FFTF was designed and constructed to meet NRC license requirements, although it is not licensed. A Preliminary Safety Analysis Report (PSAR) with the required section on QA was submitted to AEC's Division of Reactor Licensing in September 1970. Since the FFTF was owned by the AEC, the Commission had the prerogative to proceed with the FFTF program even though the Regulatory Review was not complete. The initial or limited work authorization was obtained in July 1971, and the final construction authorization came in May 1973. A report to the Advisory Committee on Reactor Safeguards (ACRS), dated December 29, 1971, and prepared by AEC Division of Reactor Licensing, stated: "Our review of the Quality Assurance Program indicates that it meets the intent of Appendix B, 10 CFR Part 50, and that adequate quality control is available at the site to assure quality in the safety-related structures."

Organization and Responsibilities. Through nearly all of the design and construction phase of the FFTF project, the responsibility for the AOQ program was delegated directly from AEC/ERDA/DOE headquarters to the prime contractor, Westinghouse Hanford Co. (WHC). Currently, the delegation of such responsibilities is from DOE Headquarters through the DOE Richland Operations Office (RL) to WHC as the prime operating contractor. The prime contractor developed the details of the AOQ program and how it was to be applied to the

FFTF project. To assure the implementation and oversight of quality responsibilities for the DOE Richland Operations Office (including FFTF), DOE RL Order 5700.1, Quality Assurance (Fremling 1980), contains the following responsibilities and authorities for QA in the DOE RL:

- Director, QA. The director develops and coordinates the RL QA program, assures that each contractor establishes an appropriate QA program according to the order's basic requirements, and assures, together with the affected RL program or project manager, that each contractor establishes an adequate QA plan for each program or project. The director also audits the RL and contractor QA activities to evaluate their effectiveness and selectively reviews contractor component and material contracts and purchase orders to assure optimum use of available offsite inspection services. The director attends periodic forum meetings with contractor QA management to review mutual QA practices and problems and to coordinate and standardize practices and procedures where appropriate. Finally, the director conducts appraisals of contractor QA activities to assure compliance with applicable requirements.

- Division Directors and Project Managers. These directors and managers determine when special considerations require a QA plan that may vary from the program required by this Order. They also verify that the contractor has identified appropriate QA requirements for individual systems, components, materials, processes, and services and that QA requirements have been considered in conceptual stages of construction projects. Finally, they verify that appropriate quality requirements are established in project design criteria and that contractor QA plans are effectively implemented.

- Director, Construction Division. This director determines when it is appropriate to assign the responsibility for the items to a prime contractor and formally delegates such responsibility and monitors the performance of the operating contractor. The director reviews and evaluates preliminary activities and plans for construction projects to verify that QA plans are appropriate and ensures that appropriate QA requirements, in accordance with this Order, are included in construction project contracts. The director also reviews, evaluates, and assures that QA activities are effectively implemented and reviews and approves key design and testing documents and plans for construction projects. Finally, the director reviews and evaluates the satisfactory completion of all required construction and testing activities before RL accepts a new facility or major modification, and he/she accepts the facilities for the government when all requirements are satisfied.

- Director, Procurement Division. This director takes the contractual actions required to support the Directors, Quality Assurance, Construction and Program Divisions and Project Offices in implementing the responsibilities and authorities delegated above.

- Responsibilities and Authorities of Contractors. The contractors develop a generic QA program and implementing procedures for DOE and other government agency-sponsored programs and projects performed in accordance with this Order, and they prepare and implement QA plans for assigned projects and programs. They also verify effective implementation of the QA program and plans for assigned programs and projects and monitor the performance of an A-E and/or construction contractor, as delegated by the Director of the Construction Division.

QA Program. The basic requirements of the QA criteria used on the FFTF project, RDT F 2-2, Quality Assurance Program Requirements, and RDT F 2-4, Quality Verification Program Requirements, are essentially the same as the other recognized criteria given in Appendix B, 10 CFR 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. The AOQ program that has been applied on the FFTF project throughout its life is all-inclusive (pertaining to the entire facility), yet flexible. This program and the management philosophy established and followed during the design, construction, fuel fabrication, testing, and startup of the FFTF (i.e., that the line organization has the responsibility and that QA is integral to the work) has resulted in a plant that is exceeding its established operational goals.

During the review of the FFTF AOQ program, four QA functions were identified that appeared to be key to the project and that may have applicability to the NRC. These functions are QA classifications, design review levels, data-type QA classifications, and readiness reviews, and are discussed separately below.

- QA Classifications. QA classifications were established for varying levels of effort necessary to provide a controlled system that assures a safe and properly functioning facility or component. This enabled AOQ efforts to be concentrated on the items and systems crucial to the reactor and its supporting facility.

  Items, components and systems provided for or used in the FFTF were evaluated by a set of factors and assigned a QA classification or type. These types/classifications were used as guidelines for applying appropriate QA efforts for the various components and elements of the system. During much of the construction phase, three levels of QA were applied. The most extensive application was in accordance with RDT F 2-2, the second was in accordance with RDT F 2-4, and the third represented standard commercial practices. This was later expanded to four levels. The four levels or types of QA classifications and the factors to be considered in assigning QA classifications are shown in Table D.2, extracted from the Westinghouse Hanford QA Manual.

TABLE D.2: Definition of FFTF QA Classifications (Hanford Engineering Development Laboratory 1982)

The following definitions are established for the various QA classifications. They may be used in determining the level of quality assurance effort necessary to provide a controlled system that will assure that the facilities and/or components function safely and properly.

Some factors to be considered in assigning QA classifications include the following:

1. the consequence of the item's malfunction or failure
2. the item's design and fabrication complexity or uniqueness
3. the need for special controls and surveillance over processes and equipment
4. the degree to which functional compliance can be demonstrated by inspection or test
5. the item's history and degree of standardization
6. the difficulty of the item's repair or replacement and the associated cost, including procurement lead time.

DEFINITION OF QA CLASSIFICATIONS

Type I - Applies to items that are highly or moderately complex whose failure can have a direct effect upon operability, performance or safety. Items, which if failed, could cause or fail to prevent an incident affecting health and safety, are also included in this classification. Typical examples of Type I include reactor core components, fuel handling equipment, and high-level radioactive waste systems.

Type II - Applies to items that are moderately complicated and whose failure can have a significant impact on the validity of development test results, operation, performance or safety. Items, which if failed, could cause an incident affecting the health and safety of personnel on the Hanford Site are also included in this classification. Typical examples of Type II include radiation monitors, pressure-retaining components, and HVAC equipment for contaminated zones.

Type III - Applies to items of standard or customized design of a unique but simple nature whose consequences of failure are unlikely to be severe, and/or which can be readily controlled through simple inspections or tests. Typical examples of Type III include standard electronic equipment and air sampling monitors.

Type IV - Applies to activities or items with minor consequences of failure, whose quality is adequately assured through undocumented examination by the requester, such as temporary buildings, roads and fences, and commercial tools.

- Design Review. All FFTF design contractors and suppliers, as part of their QA programs, were required to submit a plan for performing independent design reviews, for submitting design review reports, and for assuring resolution of problems revealed by the design reviews. Formal design reviews were identified in the design contractor's or supplier's project planning documents, and the meetings were scheduled sufficiently in advance to avoid unnecessary delays in major milestones. Design reviews were to be regarded as contract "HOLD" points; for example, as a prerequisite to requesting approval of a design package to be released for fabrication.

During the early stages of a design development, the FFTF cognizant engineer responsible for developing a design was required to review the preparation of design drawings, preferably at the design contractor's office, and to verify the understanding of the basic approach and the content of the design packages. The design contractor was required to notify WHC when a design had reached the agreed-upon state for a meeting (Preliminary Design Review).

All principal design documents, such as specifications, drawings, and analyses, were reviewed and evaluated by the cognizant design contractor, before release, to verify the completeness and adequacy of design criteria and contract requirements. When a document was submitted, FFTF project management was required to verify consistency with the functional requirements of the system design descriptions and with the specific requirements of the design application and submit comments (when appropriate) to the originator.

Each design contractor was required to define a system for selecting design review participants, for defining the design and data to be reviewed, for stating proposed objectives and the agenda, and for identifying the review chairman, and time and place of the meetings. After the design contractor determined that a design had reached a point requiring project approval, the responsible design organization was required to call the scheduled formal design review meeting.

The cognizant design contractor or supplier was responsible for taking appropriate action to ensure that all action items resulting from the design review are promptly and adequately resolved.

The design review system was integrated with the design release control system. Design review plans provided for successive reviews and corresponding release depending upon the Data Type Classification. The lowest level was suppliers, next was the cognizant Design Contractor, then the FFTF Project, and finally DOE. The most sensitive design terms were reviewed by each level and required DOE approval. The least sensitive could be reviewed and approved by a supplier. This is discussed further below.

- Data Type Classifications and Releases. The basic FFTF procedures and requirements for data review and initial project release are discussed in this section. To determine the level of approval required for initial project release, all FFTF Principal Design Documents were divided into the following data types:

- Data Type 1 included key controlling documents and drawings, such as Safety Analysis Reports, System Design Descriptions, plot plans, piping and instrument diagrams, major assemblies, and general plan arrangements.

- Data Type 2 included documents and drawings such as engineering studies, design or stress reports, quality control procedures, piping and mechanical layouts, radiation zoning, control logic diagrams, and instrument locations.

- Data Type 3 included documents and drawings such as detailed design drawings, and other supporting design documents not classified as Data Type 1 or 2.

- Data Type 4 included supplier drawings or other documents not otherwise classified as Data Types 1, 2, or 3.

All changes to principal design documents were subject to a categorization program to determine the impact of the change and the appropriate level of approval required for project release. The originator of the document change made the first determination of the impact level. Three impact levels were used in the classification. For impact level 1, the originator had to obtain the FFTF cognizant engineer's and DOE's approval. Impact level 2 required approval of the FFTF cognizant engineer while impact level 3 changes could be approved and released by the design contractor.

- Readiness Reviews. Another AOQ or program management function used at the FFTF is that of a project review board or readiness review. In a new or modified facility or system, the coordination of many elements and attention to every detail is required to assure that it is ready to proceed to the next step safely and effectively. Project or readiness review boards have been used at the FFTF since 1976. They were applied on system startup tests and are now being used during reactor shutdowns and startups. Guidance for the current readiness review process at FFTF is given in detailed procedures. Those procedures basically direct that a readiness review be conducted to document line management's certification of the readiness of 1) the FFTF plant, 2) the operating staff, and 3) the support groups to conduct startup and operation following a schedule outage. In addition to FFTF line management, personnel from outside the FFTF plant organization are on the Review Board. Each review is specific and addresses the status of the Operations and Test Plan, the Reload Design Report, refueling documentation, significant plant repair and maintenance activities, major plant changes, engineering system readiness assessments, reactor and industrial safety issues, technical specification/procedural changes, and the plant's transition into the operational mode.

In addition, special emphasis topics may be included in a review at the discretion of the Review Board. Other assessments of a broader nature, such as the status and quality of engineering instructions, are performed as part of the system of routine audits conducted by FFTF plant, safety, and quality assurance organizations.

D.4.2.3 Gas Centrifuge Enrichment Program

This part of the study addresses the QA programs followed by DOE and associated organizations on the design, construction, testing, and startup of the Gas Centrifuge Enrichment Plant (GCEP) and related development facilities. In addition to reviewing the publicly available documents about the GCEP program, interviews were conducted with DOE staff and some of their contractors at the Oak Ridge Operations Office (ORO), Oak Ridge, Tennessee, and at the GCEP construction site near Portsmouth, Ohio. The Centrifuge Program Development Facility (CPDF) was also visited.

Background. Construction of the GCEP production facilities near Portsmouth, Ohio, began in the spring of 1979. A "cascade" of production machines is scheduled to go into operation in the spring of 1984. Certain aspects of the fabrication and construction activities have been reported to be ahead of schedule. In 1982, the CPDF was placed in operation. Although identified as a development facility, the CPDF is a large structure and its startup was the culmination of an involved engineering and construction effort. The project was completed ahead of schedule and under budget, and the QA program that was applied during the CPDF project was felt to be a positive factor in putting a workable facility in operation.

The QA program or system being applied on the GCEP is integrated into the management realm where the QA elements are combined with other management requirements. A series of documents has been developed to provide general requirements on and specific instructions for establishing and executing the various management aspects during the design, fabrication, construction, installation, startup, operations and maintenance of structures, components and systems of the GCEP.

Organization and Responsibilities. The DOE field offices have the overall responsibility and authority for assuring that the required QA activities of contractors under their direction are implemented. Thus, the field offices have a direct relationship with organizations such as Union Carbide or Stone and Webster, which have prime contracts with DOE. For other suppliers, manufacturers, or contractors under contract to a prime contractor, DOE QA personnel have contact only through the prime contractor. The DOE can and does authorize prime contractors to administer DOE contracts, including the QA functions, with other organizations.

Some DOE-ORO staff members who are involved in AOQ functions administratively report to the Quality Reliability Division under the Office of Assistant Manager for Safety and Environment. Others functionally report to the various divisions within an operational office such as Office of Assistant Manager for Enriching Operations and Development. The majority of DOE-ORO staff involved with the various GCEP QA functions are permanent personnel identified as professional QA or nuclear engineers. A member of the QA division is assigned to

GCEP QA on a full-time basis; however, those in the operations and development office handle QA functions along with other engineering and program management assignments.

The responsibilities and authorities for QA policy coordination and overview and for developing, implementing, or evaluating QA activities in support of design and construction of DOE programs at Oak Ridge (including GCEP) are contained in OR 5700.6 Quality Assurance - ORO Site Implementation Plan:

- Contracting Officers and Contracting Officers Representatives (COs/CORs) for AE and Construction. Provide contactors with QA requirements, assessments, and plans for implementation. Obtain contractors' comments and contributions to assessments and plans for follow-on participants. Provide copies of assessments and plans to the Director, Q&R Division, for comment and concurrence before approval. Report significant quality problems and unusual occurrences. Obtain participation of cognizant operating contractor personnel during design and construction to identify potential problems with satisfactory performance in service.

- Director, Procurement and Contracts Division. Assure that contracts contain provisions for AOQ of materials and services. For procurement contracts exceeding $1,000,000, obtain concurrence of the Director, Q&R Division, on requirement for AOQ.

- Director, Quality and Reliability Division. Manage the ORO QA program. Establish QA policy for implementation by ORO program and project divisions. Develop and provide specific guidance for application of QA to all ORO programs and projects, except weapons components and assemblies. Review and approve selected contractor policies and plants for QA. Maintain surveillance of contractor activities and assure compliance. Perform management appraisals to verify adequacy and effectiveness of contractor QA programs; coordinate appraisals with and utilize resources of other cognizant DOE organizations, as appropriate. Investigate significant quality problems, identify quality-related issues, and cause corrective actions to be taken by responsible contractor organizations through COs/CORs and project managers.

GCEP QA Program. The QA program that has been developed at Oak Ridge Operations (ORO) and that is being applied on GCEP programs is an integral part of the project's planning and management activities. QA is included in a "systems" approach from the start of a particular activity. The systems approach addresses the quality, safety, reliability, operability, and maintainability of all components, equipment, and processes involved. Each architect-engineer (AE) or contractor must have a formal program for deliberately and systematically assuring the performance of equipment and facilities. Each of these programs must 1) show management support and concern of QA, 2) emphasize prevention of major problems, 3) provide the means for all employees to understand their roles, and 4) provide a basis for measuring the effectiveness of QA.

A main aspect of the GCEP QA program is the required evaluation of failure consequences as well as the probability of failure of a component, equipment, or process. This procedure provides the means to establish the criticality of an item within a system and the relationship of that system to the project and permits the concentration of QA activities where needed most.

If the risk of failure is high or unacceptable, special attention to prevent failure is required and specific QA actions are prepared to reduce the risk to an acceptable level. Formal planning is required to prevent potential quality problems when the risk of failure is not acceptable. These plans assure adequate considerations of actions to prove quality of development, design, procurement, fabrication, construction, operation, or maintenance and to find quality problems in time to minimize their impact.

Another aspect of the GCEP systems QA program that is considered to be beneficial is the requirement that all participating groups, including AEs, take part in the early planning and participate in all the various phases of the project.

The schematic in Figure D.2 depicts some of the QA elements which are fundamental to the ORO QA program. This figure shows that QA or the assurance of quality is used in a much broader sense than the NRC traditional use of QA requirements: the ORO approach incorporates the QA elements into the overall management of the project.

QA Program Implementation GCEP QA methodology and responsibilities are specified in ORO-EP-105, GCEP Quality Assurance Requirements. Overall responsibilities and authority of project participants are defined in ORO-EP-103, GCEP Project Management Plan, and ORO-EP-116, System Engineering Management Plan. The Deputy Manager for Enrichment Expansion Projects is responsible for establishing and executing the QA Program and assigning parts of it to other organizations, although he retains responsibility for overall program effectiveness.

The basic elements of ORO-EP-105 are as follows:

- Each project participant must have a formal program for assuring quality of equipment and facilities.
- Concern for quality must be visible and should receive management attention comparable to that given to costs and schedules.
- To maximize effectiveness, the QA program must be selectively applied to emphasize prevention of major problems.
- The program must include provisions that assure that each employee clearly understands this role in providing assurance of quality.
- To provide a basis for judging the effectiveness of the QA program, the costs of significant quality problems must be documented and presented to appropriate levels of management.

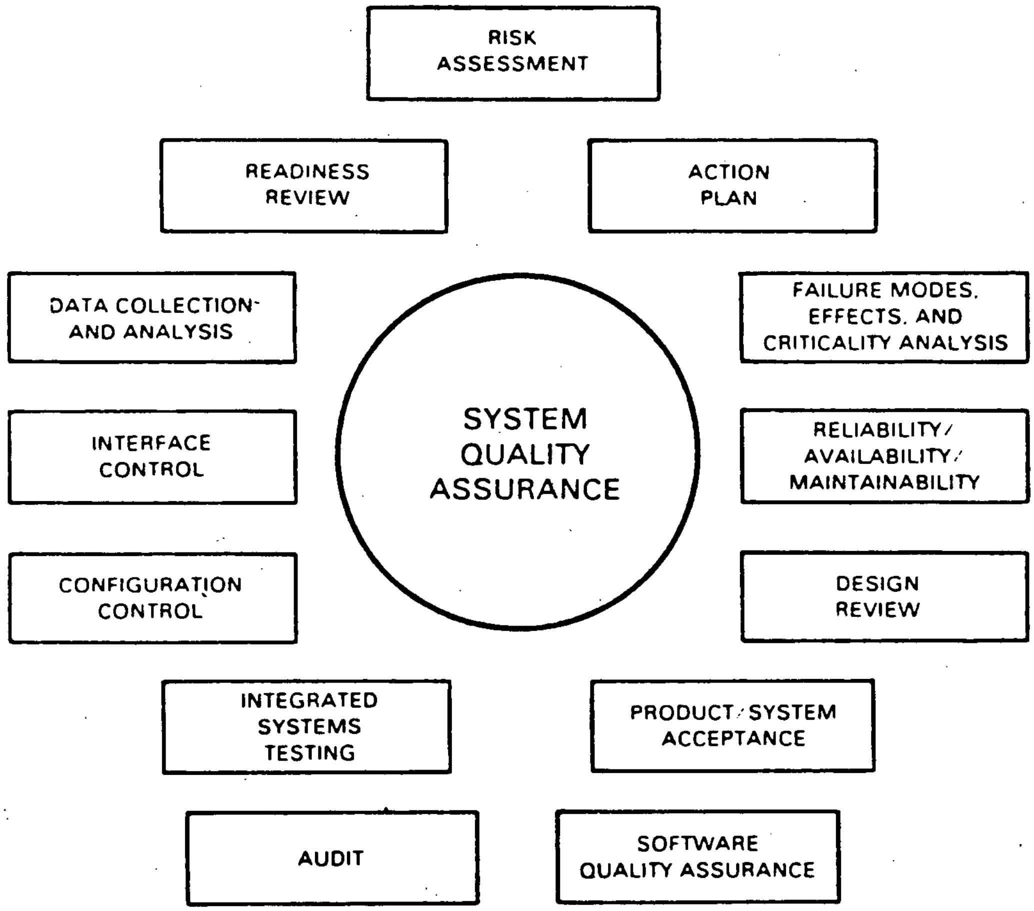

FIGURE D.2. Quality Assurance Elements

The system engineering function for the GCEP covers all of the system requirements for definition, analyses, verification, technical reviews, and other system efforts, including QA, necessary to assure the optimum balance of performance, safety, costs, and scheduling. The system engineering function will support the design, installation, startup, and operational phases of the GCEP. The principal objectives of the system engineering function are as follows:

- to assure that the system requirements of the GCEP process are adequately specified and documented and that due consideration and emphasis is given to all aspects of the project
- to provide system analyses of the designs as they progress to assure that system requirements are met and that GCEP interfaces are compatible
- to assist in defining programs for the necessary and sufficient verification of GCEP systems

- to integrate reliability, maintainability, logistics, safety, producibility, and other related specialties into a total system effort.

QA Classification. At ORO, quality is defined as "fitness for intended use." Accordingly, the GCEP project's basic approach to quality assurance is to assure that the plant's equipment and facilities will be of a quality consistent with their importance to plant operation, reliability, and safety. Therefore, a formal evaluation is required for each system or subsystem to determine the consequence of failure of equipment and facilities. Those performing the assessments are required to consider the effects of failure on safety, environment, cost, schedule, and plant reliability. If it is determined that a failure will have significant consequences and the risk of failure is unknown or unacceptable, or that the consequences of failure are so severe as to be unacceptable under any circumstances, regardless of the probability of occurrence, the item assessed is classified as "special" and a specific Quality Assurance Action Plan (QAAP) is prepared. The requirements of the QAAP are tailored to address the specific area of concern to assure that the equipment or component will function as intended and required. Items determined not to be special are classified as "routine" and come under the basic QA Plan.

QA Program Requirements. The requirements for application of QA by the GCEP contractors are identified in ORO-EP-105, GCEP Quality Assurance Requirements. This document identifies the quality responsibilities and programs for each contractor to implement. ORO-EP-105, GCEP Quality Assurance Requirements, is also structured in two distinct categories: 1) basic QA program requirements, and 2) supplementary control systems in support of quality assurance. The basic requirements apply to all major participants who are DOE prime contractors and are the primary concern of QA personnel. The supplementary controls are administered by appropriate line management.

The basic requirements as identified in ORO-EP-105 are incorporated into a QA program at the earliest practicable time consistent with GCEP schedules. Personnel from all participating groups, including quality assurance and operations, contribute to the program plans. Operations personnel are involved in the review of design and construction activities, and management of the participating organizations review the status and adequacy of the program parts.

Quality Assurance Action Plans (QAAP) are prepared by the responsible design organization for those items identified as special by quality assessments. The implementing organization is responsible for developing the plan and procedures required to accomplish the actions specified in the QAAP; for items established as routine in the QA assessment, participants are required to take appropriate steps to identify and prevent quality problems.

A Construction Critical Items List is made for each design package released or certified for construction. This list is included in the construction package.

Participants document their basic QA program in a manual or program plan and keep it current. Each manual or plan is reviewed and approved by management or upper-tier contractors.

Supplementary Control Systems in Support of QA. In ORO-EP-105, supplementary controls are grouped in the categories of design, procurement, manufacturing/fabrication, testing, and construction/installation. Under design, control requirements are noted for QA-related systems that are selectively applied based on the nature and scope of the work as well as the importance of the items and services being provided. Included are such elements as assurance that design requirements are correctly translated into design documents, interface control, design verification, design change control, and document control. ORO-EP-105 also provides appropriate quantitative and/or qualitative criteria in the form of instructions, procedures, or drawings; corrective action; quality records; and QA audits.

The procurement controls include procurement document control that provides for a supplier QA program, basic technical requirements, source inspection and audits, documentation requirements and lower-tier procurements. It also includes control of purchased material, equipment and services; corrective action; quality records; and audits of procurement activities.

For manufacturing/fabrication, the elements of instructions, procedures, and drawings; document control; identification and control of materials, parts, and components; control of special processes; inspection; and control of measuring and test equipment are noted. The elements of handling, storage and shipping; inspection, test and operating status; nonconforming items; corrective action; quality records; and QA audits are covered.

Testing includes the elements of test control; instructions, procedures, and drawings; document control; failure analysis; records; and QA audits.

Under construction/installation, the elements included are instructions, procedures and drawings; document control; control of purchases, material, equipment and services; identification and control of material, parts, and components; control of special processes, construction and installation inspection; and acceptance testing. The elements of control of measuring and test equipment; handling, storage and shipping; inspection and test status; nonconforming items; corrective action; quality records; and QA audits are also included.

The responsibility and authority to produce reliable GCEP machines and systems are delegated to contractors. From a QA/QC viewpoint, the construction management contractor, Stone and Webster, or the A-E overviews and monitors activities of their subcontractors, as well as other construction contractors under contract to the DOE. DOE Portsmouth contracts for and overviews the activities of contractors such as Stone and Webster, while DOE-ORO audits the QA activities of DOE Portsmouth and Stone and Webster.

Integration by DOIT Teams. A management team concept has been established and placed in effect at GCEP for work execution and control including quality assurance. This system is outlined in PPO-EP-104, GCEP Construction Work Package Execution and Control System (DOIT). It also establishes appropriate interactions among the many GCEP participants.

Working execution and control teams, or DOIT teams, are used to manage defined pieces of work (work packages) so they can be completed cost effectively within prescribed parameters. Currently, at GCEP four DOIT centers are in operation: DOIT-P (process facilities), DOIT-R (Recycle, Assembly, Centrifuge Training and Test Facilities), DOIT-S (site and support facilities), and DOIT-F (feed and withdrawal). Each DOIT center or team includes representatives from each of the principal and responsible participating organizations. These participants and their areas of responsibility are as follows:

Portsmouth Project Office (PPO) - General Manager
Architect-Engineer (A-E) - Engineering and Design
Stone and Webster Engineering Corp. (SWEC) - Construction Management
Operating Contractor (OC/OCPO) - Startup and Operations

In the embryonic stage, a work package (WP) is equivalent to a design package (DP). During its evolution it may encompass many DPs or combinations thereof. Regardless of evolution, type of contract, work breakdown structure, number, etc., the WP identifies a defined piece of work that is to be accomplished. Each WP includes technical requirements, quality standards, performance period, estimated cost, and how it is to interface with other WPs. The WP identifies a certain portion of the facility design by the A-E and its acceptable state before the Portsmouth Project Office (suboffice of DOE-ORO) can accept it from the constructor and to turn it over to the operating contractor for custodianship.

D.4.3 NASA Assurance of Quality (AOQ) Program

In the review of the National Aeronautics and Space Administration's (NASA) programs for safety, reliability, and quality assurance (SR&QA), extensive use has been made of previous studies on the NASA programs, which examined the possible applicability or transfer of the NASA program concepts to the NRC and nuclear power industry. These studies include Space and Missile Reliability and Safety Programs, prepared for the Nuclear Safety Analysis Center (NSAC), 1981, and the Application of Space and Aviation Technology to Improve the Safety and Reliability of Nuclear Power Plant Operations, prepared for the Department of Energy (DOE), 1980. Additional information on the NASA programs was obtained from published NASA documents and through meetings with NASA Headquarter's SR&QA staff.

The NASA approach for assuring the quality of their space and missile program is generally perceived as very successful. In only 25 years, the U.S. has probed the reaches of outer space, has had men walking on the surface of the moon, and has established a highway to space with space shuttle craft. These space projects have generally required advances in the technical state-of-the-art in many systems and subsystems.

D.4.3.1 Background

NASA was formed in 1958 (by legislation commonly referred to as the Space Act of 1958) and was given a Congressional mandate 1) to restore U.S. technological leadership, and 2) to lead the world into the space age for its peaceful benefits. NASA inherited several field installations from the U.S. Army, Navy, Air Force and the National Advisory Committee for Aeronautics. These sites include the Marshall and Goddard Space Flight Centers, Jet Propulsion Laboratory (California Institute of Technology), Cape Canaveral, Wallops Island, and Langley Research Center (NSAC 1981).

Since its origin, NASA has generally operated as a decentralized agency with the NASA headquarters responsible for the development of policy for field use. The field offices develop programs to implement the NASA policy and tailor the programs to fit and meet the peculiarities of the projects assigned to the NASA field offices. In mid-1961, a separate quality assurance organization was formed. With approximately 90% of the NASA-sponsored work performed by contractors, the QA organization initiated efforts to develop quality program requirement documents that would be used by the NASA Centers or field installations to place QA requirements on the NASA contractors. These early QA documents established basic QA policies that remain in effect today. These policies are as follows:

- Quality is the overall responsibility of the NASA Centers and cannot be delegated.
- Central direction is provided by a QA organization having responsibility and authority in each NASA Center.
- NASA QA requirements are included in NASA contracts.
- Assuring satisfactory performance in developing and maintaining system quality is the responsibility of the NASA procuring installation (NSAC 1981).

In 1967, the Apollo fire more sharply focused NASA attention on the need to assure system safety. The emphasis on systems engineering was increased. The importance and relationship of safety, reliability, and quality was recognized, and the three disciplines were coordinated and integrated. In the late 1960's, revised policy documents were issued to address revised requirements for system safety, reliability, and quality. These documents closely coordinated the safety analysis (such as hazard identification), reliability analysis (such as failure mode and effect analysis), and the quality program requirements necessary to achieve the safety and reliability performance goals.

D.4.3.2 Organization and Responsibilities

The Chief Engineer at Headquarters and the Directors of the various NASA Centers and laboratories all report directly to the NASA Administrator. The NASA headquarters' safety, reliability and quality assurance staff report to the Deputy Chief Engineer, whereas at the NASA Centers, the Director of the Safety, Reliability and Quality Assurance staff generally reports to the Center Director.

The basic responsibilities for planning, developing, conducting, and evaluating NASA programs and other activities to ensure the achievement of necessary levels of safety, reliability, and quality are identified in NHB 1700.1(V1.A), Basic Safety Manual, and NMI 5300.7B, Basic Policy and Responsibilities for Reliability and Quality Assurance. In addition, NASA documents NHB 5300.4(1A), Reliability Program Provisions for Aeronautical and Space System Contractors, and NHB 5300.4(1B), Quality Program Provisions for Aeronautical and Space System Contractors, contain specific reliability and quality program requirements for NASA contractors, while the safety requirements of NHB 1700.1(V1.A) are also applicable to contractors.

The basic NASA policy for SR&QA, as stated in the NASA policy documents, includes two objectives:

- Safety (NHB 1700.1(V1.A))

  1. Avoid loss of life, injury to personnel, damage to or loss of equipment or property, mission or test failure, and undue risk.
  2. Promote safety by instilling safety awareness in all NASA employees and contractors.
  3. Use an organized and systematic approach to identify and control hazards ensuring that safety factors are fully considered from conception to completion of all agency activities.

- Reliability and Quality Assurance (NMI 5300.7B)

  1. Plan and execute NASA activities to achieve levels of reliability and quality that are commensurate with mission objectives and overall life-cycle costs.
  2. Tailor the provisions of the reliability and quality assurance manual to the extent needed and consistent with NASA program planning. Use the NASA Procurement Regulation, NHB 5100.2, Part 14, in conjunction with the Reliability and Quality Assurance Manual for contracted effort.
  3. Define and assign reliability and quality assurance tasks to minimize duplication of resources, make effective use of ground and flight experience, and properly consider interfacing disciplines.
  4. Periodically review and evaluate plans, systems and activities for achieving reliability and quality to ensure that objectives will be met within available technology, funding and schedule constraints.

D.4.3.3 Program Requirements

Each NASA Center has the responsibility to develop and tailor programs to implement the NASA policy requirements for safety, reliability and quality for the programs and project activities assigned to that Center. To characterize the NASA program requirements for SR&QA, the NASA guidance documents for the space shuttle program were selected as examples to illustrate both the coordination and integration of NASA SR&QA. The following statement is an excerpt from the preface of NHB 5300.4(1D-1), Safety, Reliability, Maintainability and Quality Provisions for the Space Shuttle Program:

> This publication establishes common safety, reliability, maintainability and quality provisions for the Space Shuttle Program.
>
> NASA Centers shall use this publication both as the basis for negotiating safety, reliability, maintainability and quality requirements with Shuttle Program contractors and as the guideline for conduct of program safety, reliability, maintainability and quality activities at the Centers. Centers shall assure that applicable provisions of this publication are imposed in lower tier contracts. Centers shall give due regard to other Space Shuttle Program planning in order to provide an integrated total Space Shuttle Program activity.
>
> In the implementation of safety, reliability, maintainability and quality activities, consideration shall be given to hardware complexity, supplier experience, state of hardware development, unit cost, and hardware use. The approach and methods for contractor implementation shall be described in the contractor's safety, reliability, maintainability and quality plans.
>
> This publication incorporates provisions of NASA documents: NHB 1700.1, NASA Safety Manual, Vol. I; NHB 5300.4(1A), Reliability Program Provisions for Aeronautical and Space System Contractors; and NHB 5300.4(1B), Quality Program Provisions for Aeronautical and Space System Contractors. It has been tailored from the above documents based on experience in other programs. It is intended that this publication be reviewed and revised, as appropriate, to reflect new experience and to assure continuing viability.

NHB 5300.4(1D-1) stipulates the NASA approach for SR&QA, and requires the following:

- thorough planning and effective management
- definition of the major safety, reliability, maintainability, and quality assurance tasks and their place as an integral part of the design and development process
- evaluation of hardware safety, reliability, maintainability and quality through analysis, test, review, and assessment

- timely status indication by formal documentation and other reporting to facilitate implementation of the safety, reliability, maintainability, and quality assurance efforts

- compatible requirements among manufacturing, test and operational sites.

The following three sections present an overview of the NASA program requirements for safety, reliability and quality assurance for the space shuttle program.

Safety. According to NASA program requirements, a safety plan must be developed and must include a description of the approach for identifying, eliminating and/or controlling potential safety hazards that could lead to injury, loss of personnel, and damage or loss of flight or ground hardware throughout the program's complete cycle. The safety plan will integrate and describe the relationship of all safety activities. The safety requirements and tasks are to be reflected as appropriate in other program plans.

The basic elements of a NASA safety plan are summarized below (DOE 1980):

- System Safety Analysis. Establish and identify procedures and instructions that will be used to execute all safety analyses. Perform system and safety analyses to assure the following:

  - Safety is to be designed into the product. Known hazardous conditions that cannot be eliminated through equipment design or operation procedures are to be controlled or reduced to an acceptable level. Residual hazards shall be tracked and identified to NASA.

  - Hazard level classifications are to be used to provide a continuous tracking and status of severity to reduce catastrophic and critical hazards to controlled levels within the constraints of risk management.

- System Safety Guidelines and Constraints. Develop and establish system safety guidelines, constraints, and requirements to guide the vehicle system's design, ground support equipment design, and operations planning. These criteria shall satisfy programmatic guidelines and constraints, system safety goals, and other top-level safety objectives.

- Safety and Trade Studies. Specific, inherently hazardous characteristics of the alternatives being considered shall be identified. Rationale shall be documented to support the selected concept and to demonstrate that it includes the optimum safety provisions consistent with program objectives, risk management, performance, cost, and schedule.

- Hazard Analysis. Perform a qualitative hazard analysis to identify hazards and to assure their resolution. Hazards shall be defined and classified by hazard levels. Conduct periodic performance and refinement of hazard analysis and periodic assessment of achieved versus specified requirements. All hazards, including those resulting from failures, irrespective of subsystem or component redundancy, shall be analyzed. In addition to hazards resulting from failures, those emanating from normal or emergency equipment operations, environment, personnel error, design characteristics, and credible accidents shall also be analyzed. Identify and eliminate or control any failures or malfunctions that could independently or collectively present a hazard to interfacing hardware, and assure that normal operation of a hardware, item cannot degrade the safety of interfacing hardware or the total system. Early hazard analysis emphasizing design shall be the baseline of an expanded analysis. The hazard analysis shall be updated as the program progresses, providing continuity and covering the interrelated areas of design, operations, and vehicle subsystem integration.

- Human Engineering. Procedures shall be developed to assure the application of safety-related human engineering principles during design, development, manufacture, test, maintenance, and operation of the system or subsystem to minimize human error.

- Interface with Other Program Functions. Safety shall be coordinated and integrated with other program functions to avoid overlaps and conflicts among the technical disciplines, and to establish an integrated effort. This coordination shall include the delineation of responsibilities, management structures, joint analyses, reporting procedures, feedback of test data and corrective actions, use of failure mode and effects analyses, single failure point summaries, or other analytical techniques to identify hazards.

- Waivers and Deviations. For proposed waivers and deviations, the contractor shall establish a way to analyze the safety impact.

- Hazard Data Collection, Analysis, and Corrective Action. Using existing data systems wherever practical, a system for reporting hazards, data storage, and feedback of corrective action shall be formulated.

- Specifications and Procedures Review. Specifications and procedures for manufacturing, testing, and operations shall be reviewed to assure that these activities do not negate the inherent safety of the design.

- Review of Changes. When changes are proposed for equipment design or procedures, identify and resolve hazards that may be introduced into the system. Residual hazards shall be identified as part of the engineering change evaluation.

- Postflight Evaluation. System safety organizations shall participate in postflight reviews and a safety evaluation shall be made in cases where anomalous conditions are revealed. This safety evaluation will provide guidance in planning future missions and establishing necessary corrective action to reduce hazards.

Reliability. According to NASA program requirements, a reliability plan is to be developed in conjunction with other program plans. Reliability is an integrated part of the design and development process and is to include the evaluation of hardware reliability through analysis, review, assessment, and timely status reporting. The three major elements of the reliability program are reliability management, reliability engineering, and testing [NHB 5300.4(1D-1)].

NHB 5300.4(1A), Reliability Program Provisions for Aeronautical and Space System Contractors, prescribes general reliability program requirements for NASA contracts involving the design, development, fabrication, testing and/or use of aeronautical and space systems and elements thereof. Basically, it stipulates that the contractor will maintain a reliability activity planned and developed in conjunction with other contractor elements. Reliability functions will be an integral part of the design and development process and will include the evaluation of hardware reliability through analysis, review, and assessment. The contractor will provide, maintain and implement a Reliability Program Plan that describes how compliance will be ensured with the specified reliability requirements of engineering, design, failure mode analyses, testing and reliability assessments.

A summary of some of the major elements of the NASA reliability program is given below (DOE 1980).

> The reliability management task involves the identification of a reliability organization that has unimpeded access to top management including main line and program managers ... [NASA requires] each contractor to conduct audits of their internal reliability and those of his suppliers ... [to] evaluate progress and effectiveness and ... determine the need for adjustments or changes in activities.
>
> Each major contractor must ensure that the reliability of system elements from subcontractors and suppliers meets the requirements of the overall system. The level of reliability is tailored to the supplier.
>
> The reliability engineering tasks involve development of reliability design criteria for each subsystem, a system for receiving and concurring on design specifications and changes, and assuring that no subsystem or component specifications violate reliability design criteria ....
>
> The most in-depth analysis and example of reliability engineering disciplines comes in the area of establishing a system for conducting Failure Mode and Effects Analysis (FMEA) and the control of the

results of this analysis, which are in the form of Critical Item Lists (CILs) of single failure points ....

NASA Reliability Engineering establishes the fundamental requirement for contractors supplying major space components to prepare design FMEAs at the lowest levels of system definition required to support potential uses, e.g., testing, failure reporting and corrective action, and preparation of mandatory inspection points. FMEAs must be performed to the 'black box' level and within the 'black box' to pursue all critical functions ... The FMEA includes an integration of all flight hardware, including government furnished equipment and essential launch ground equipment.

Contractors must support the internal and supplier's design reviews at the system, subsystem, and component levels as well as NASA design and readiness reviews. These reviews include the preliminary Design Review (PDR) which covers the system concept; the Critical Design Review (CDR) which is accomplished when the design is about 90% complete and components are ready for fabrication; the Design Certification Review (DCR) which is accomplished by NASA Headquarters; and, finally, the Flight Readiness Review (FRR) which determines that the equipment is ready for flight.

In summary, the NASA reliability technique includes:

- A well organized and managed reliability program.
- Defining and implementing tasks that prevent problems early in the program.
- Establishment of programmatic controls with required formatted documentation.
- Establishment of key points in the program to check and review progress and problems.
- Strict attention to detail by all organizations.

Quality Assurance. As for safety and reliability, a quality plan is to be developed in conjunction with other program plans. The elements of the quality plan are somewhat similar to the elements of 10 CFR 50, Appendix B, which is required for nuclear power plants. The NASA quality program as outlined in NHB 5300.4(1D-1) and NHB 5300.4(1B) is to do the following:

- demonstrate recognition of the quality aspects of the contract and an organized approach to achieve them.
- ensure that quality requirements are determined and satisfied throughout all phases of contract performance, including preliminary and engineering design, development, fabrication, processing, assembly, inspection, test, checkout, packaging, shipping, storage,

maintenance, field use, flight preparations, flight operations, and post-flight analysis, as applicable.

- ensure that quality aspects are fully included in all designs and are continuously maintained in the fabricated articles and during operations.

- provide for the detection, documentation, and analysis of actual or potential deficiencies, system incompatibility, marginal quality, and trends or conditions which could result in unsatisfactory quality.

- provide timely and effective remedial and preventive action.

Also, the contractor will prepare, maintain, and implement a Quality Program Plan that describes how the contractor will ensure compliance with cited quality requirements. The Quality Program Plan will be submitted as required by the Request for Proposal or Contract. The plan format shall be readily identified with each cited requirement. The plan shall cover all quality program activities for the time period or phase authorized, be updated periodically and resubmitted, as specified in the contract, and serve as the master planning and control document.

NHB 5300.4(1B), Quality Program Provisions for Aeronautical and Space System Contractors, identifies the quality program requirements for NASA aeronautical and space programs, systems, subsystems and related services. Basically, the contractor will maintain an effective and timely quality program planned and developed in conjunction with all other contractor's functions necessary to satisfy the contract requirements.

D.4.3.4 Program Implementation

NASA Centers are to invoke the requirements of the reliability and quality assurance manual to the extent required and consistent with program planning in procurements of aeronautical or space systems, launch vehicles, spacecraft, associated ground support equipment or elements thereof to ensure the required high quality of materials, parts, components and services; to design reliability into aeronautical and space systems; and to prevent degradation of the design's reliability through the succeeding steps from fabrication to end use. Because their programs require delivery of only small numbers of each system, operate under tight schedules, and require high reliability in the first, as well as subsequent systems, NASA has developed and implemented a program wherein contractors and suppliers use a thoroughly disciplined, systematic approach to safety, reliability, and quality.

NASA requires that engineering designs be essentially completed (90 to 100%) and reviewed prior to starting fabrication work. Further, in-depth, detailed "readiness reviews" are conducted at key points in a program before proceeding with the next phases or steps. These reviews assure that all changes and discrepancies have been properly addressed and resolved.

D.4.3.5 Coordination of Programs

The emphasis of NASA on safety, reliability, and quality assurance programs appears to stem from the definite commitment to coordinate and integrate these programs to achieve the common overall program objective--a safe, reliable product with the necessary level of quality to meet program performance objectives. In DOE (1980) there is a discussion on the NASA system safety approaches and reasoning or rationale behind these approaches. Listed below are a few of these features that appear to be applicable to the "entire systems" approach used by NASA to coordinate and integrate the safety, reliability and quality assurance programs and plans.

- The complexity of systems, subsystems, and components under extreme and varying environment and application conditions places heavy demand on safety systems. The inherent complexity of the NASA flight hardware systems demands technical and analytical techniques of considerable sophistication to identify and solve problems.
- The need to focus considerable attention on the safety considerations arising out of total systems effects cannot be discovered by considering portions of the system independently.
- Assure that the safety aspects of the mission under normal conditions and under mission failure conditions are adequate.
- Know the hazardous characteristics of the system, including operation under all environmental conditions during design, manufacture, test, transportation, storage, and operation. "System" includes the hardware, flight and ground support equipment/electrical support equipment, the facilities, and the procedures that are used to operate and test the system.
- Eliminate, insofar as possible, these hazards. If the hazards cannot be eliminated, take all practical steps to control them. These steps include both hardware and software considerations.
- Recognize that the management responsibility for achieving system safety flows along program organizational lines.
- Keep in mind that the desired results from system safety activities are to minimize risks to the maximum practical extent and apply the knowledge of these risks to management decisions. Also, assure an understanding at all management levels as to the risks being incurred by testing, transporting, or operating the system or portions of the system.

D.4.4 U.S. Shipbuilding Assurance of Quality (AOQ) Programs

This section discusses the AOQ programs for both U.S. Naval shipbuilding and commercial shipbuilding. For each, the program requirements and implementation are described.

This study was based totally on publicly available information obtained from a comprehensive review (including computerized literature data base searches) of pertinent references. Sources for these references included the Naval Sea Systems Command Library, the Naval Sea Systems Command Directives, the Defense Logistics Agency, the National Technical Information Service, the U.S. Department of Transportation Library (including both Maritime Administration and U.S. Coast Guard Material), and the American Bureau of Shipping Library.

However, to validate more completely the material presented here, as well as to expand the material collected so that it describes in greater detail how the programmatic aspects actually work, an outside group with technical experience on U.S. commercial and naval shipyard operations (COMEX) reviewed and expanded the material.

D.4.4.1 U.S. Naval Shipbuilding AOQ Program

The U.S. Naval shipbuilding program involves both nuclear and non-nuclear ship construction. Such construction uses many of the same kinds of materials, construction techniques, and skills used in the civilian commercial nuclear industry. The potential for hazard to the general public and a strong governmental involvement closely relate the two programs.

Background. Before 1960, no formally established quality assurance program existed in Naval or private shipyards. In November of 1960, the Bureau of Ships (now Naval Sea Systems Command - "NAVSEA") published an instruction that formally established a quality assurance program in the shipyards. A Quality Assurance Division was formed in the Production Department (which is primarily responsible for all phases of ship construction in the yard) partly by bringing together existing functions, including inspection and test sections, laboratory functions, and the welding engineers. In the Nuclear Power Division that was set up in some shipyards, there was also a responsibility for quality control functions for all operations involving nuclear power.

In 1966, the publication of a revised edition of the Standard Regulations established a mandatory Quality and Reliability Assurance Department. From 1966 to 1975, various instructions, notices and publications addressing the assurance of quality and reliability were promulgated by the Defense Department, NAVSEA, Naval shipyards, private shipyards and commercial vendors. By 1975 every Naval shipyard and all private shipyards performing work for the Navy had quality control and assurance instructions and manuals. Areas such as the nuclear propulsion program or areas of specific interest or having special, more rigorous requirements or problems had their own instructions, which amplified these basic manuals and directives.

Quality Program Organization and Requirements. The AOQ program for U.S. Naval ship construction is based on Title 32 of the Code of Federal Regulations (National Defense) DAR Section XIV, Procurement Quality Assurance. This defines the government function by which it determines whether a contractor has fulfilled its contract quality and quantity obligations. The contractor is responsible for controlling product quality and for offering to the government for acceptance only those supplies and services that conform to contract requirements. When required, the contractor also must maintain and furnish substantiating evidence of this conformance.

The organization responsible for technical requirements (e.g., specifications, drawings and standards) prescribes inspection, testing, or other contract quality requirements that are essential to assure the integrity of products and services (32 CFR). Systematic control of manufacturing processes by the producer is also an essential prerequisite for assuring the quality of such items (32 CFR). However, criteria for applying contract quality requirements can be dependent on each item's character, importance, and application.

The general framework for the regulations currently governing the assurance of quality program for the U.S. Naval ship construction program, both nuclear and non-nuclear, is shown in Figure D.3.

Three military standards/specifications form the implementing basis (32 CFR) for Department of Defense assurance of quality programs: MIL-STD-109B, Quality Assurance Terms and Definitions; MIL-Q-9858A, Quality Program Requirements; and MIL-I-45208A, Inspection System Requirements.

- MIL-STD-109B Quality Assurance Terms and Definitions. The intent of this standard is to ensure that the Department of Defense quality assurance organizations are able to implement policies based on a commonality in language.

- MIL-Q-9858A Quality Program Requirements. This specification is applicable to the Department of the Army, the Navy, the Air Force, and the Defense Supply Agency. It requires the establishment of a quality program by all contractors furnishing equipment, systems, subsystems, and/or services to the Department of Defense. Commonly referred to as "MIL-Q," this document allows the Supervisor of Shipbuilding, Conversion, and Repair (SUPSHIP) organizations to direct the contractor to establish a quality control and assurance program for a specific procurement in excess of standard contractual obligations. When invoked, MIL-Q requires the contractor to establish the programs and requires the Government Representative, in this case SUPSHIP, to approve and monitor the program.

  The complexity of such a program varies, depending upon the work being performed by the contractor. For example, private shipyards engaged in construction of nuclear submarines typically have quality assurance organizations and programs at least as sophisticated as those of Naval shipyards. On the other hand, a private yard engaged only in constructing or repairing small auxiliary vessels such as tugs and barges would not need nearly as complex an organization to satisfy MIL-Q. In April 1965, the Assistant Secretary of Defense (Installations and Logistics) published the Quality and Reliability Assurance Handbook (H 50), which provides general guidance to personnel responsible for evaluating a contractor's quality program when Military Specification MIL-Q-9858A is invoked in the contract.

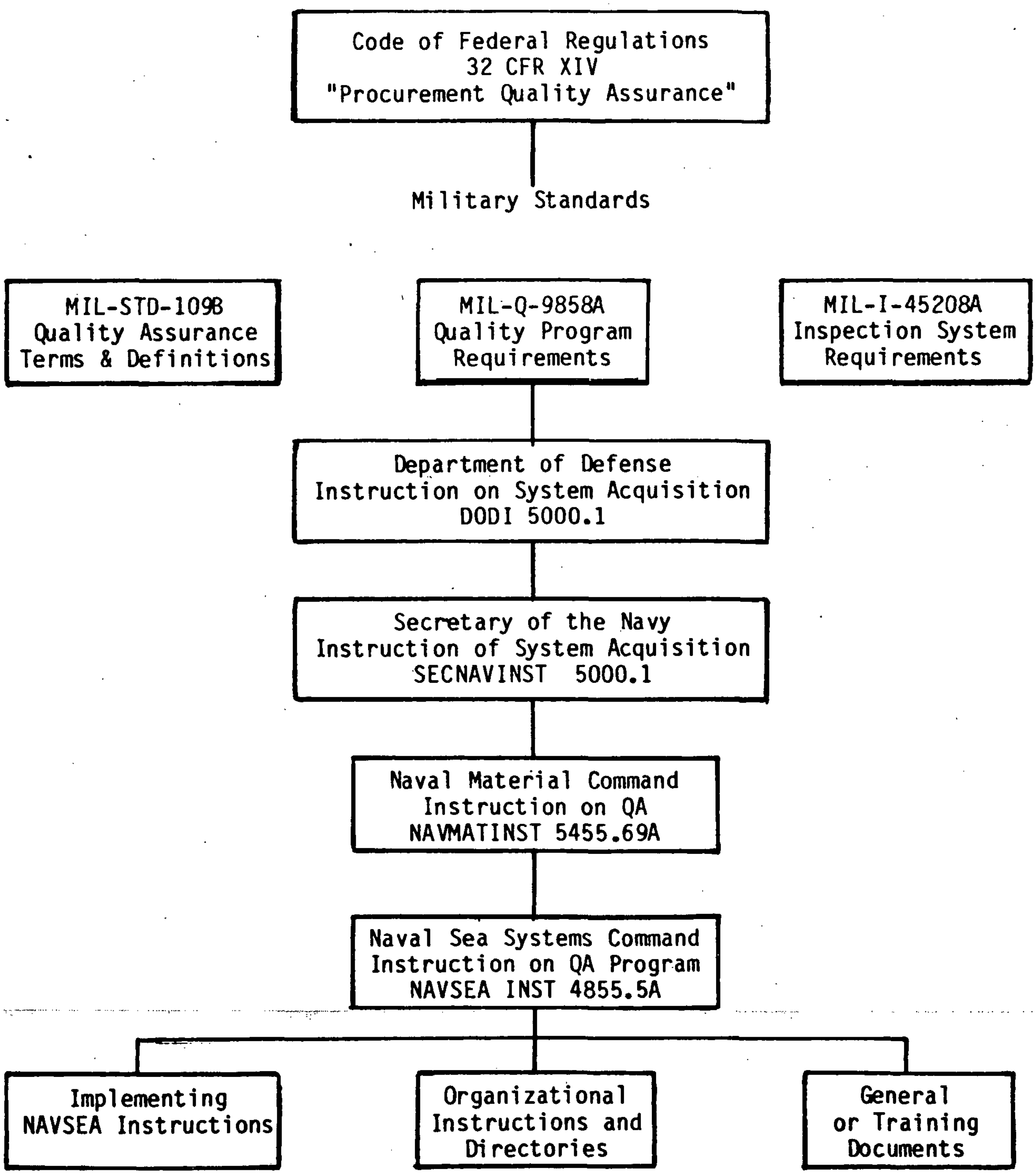

FIGURE D.3. Regulations for the Assurance of Quality Program for the U.S. Naval Ship Construction Program

- MIL-I-45208A - Inspection System Requirements. This specification establishes requirements for the inspection and tests that the contractors must perform to substantiate product conformance to drawings, specifications and contract requirements and to all inspections and tests required by the contract. These requirements are in addition to those inspections and tests set forth in applicable specifications and other contractual documents. Commonly referred to as "MIL-I," this document is similar to MIL-Q in intent, use and assignment of responsibility. Like MIL-Q, the contractor's efforts to satisfy MIL-I requirements varies with the specific procurement. Again, the contractor must satisfy SUPSHIP that compliance has been achieved and is being maintained adequately. MIL-Q and MIL-I interrelate in that in satisfying the requirements of MIL-Q, a contractor may have also satisfied MIL-I requirements.

Program Implementation. The AOQ program is directly administered by the Naval Material Command, Naval Sea Systems Command, and the Naval shipyards.

Within the Navy, the Naval Material Command implements the overall procurement QA program in accordance with NAVMATINST 4355.69A. This document is identical to that used for the Defense Supply Agency (DSAM 8200.1). Army (AR 702-4), Air Force (74-15) and Marine Corps (MCOP 4855.4A). The Deputy Chief of Naval Material for Reliability, Maintainability and Quality Assurance (MAT 06) is responsible for AOQ programs regarding the acquisition of naval material, and has four components reporting to him: (1) Program Assessment Division (MAT 061), (2) Reliability and Maintainability Division (MAT 062), (3) Quality Assurance Division (MAT 063), and (4) Manufacturing Technology Division (MAT 064).

The Naval Sea Systems Command reports to the Naval Material Command and serves as the coordinator of shipbuilding, conversion, and repair for the Department of Defense; and coordinator of ship repair and conversion of the Department of Defense/Department of Commerce.

In July 1975, the Naval Shipyard Quality Program Manual, NAVSEA 0900-LP-083-0010, was promulgated (NAVSEA 1982). This manual established the minimum quality program requirements for constructing, converting, modifying, overhauling, and refurbishing Naval ships and craft. This generic document addresses general responsibilities, technical data, work instructions and authorizations, procurement quality control, material control, process controls, metrology and calibration, inspection and verification, corrective action, preventive action, audits, and training. By mid-1977 the provisions of this manual had been implemented in Naval and private shipyards.

Although the requirements for quality programs are reasonably well consolidated in NAVSEA 0900-LP-083-0010, countless amplifying documents and instructions exist that are more specific, detailed or tailored to the specific needs of ship operators, ship or system types. Separate programs that are distinct from the overall Navy AOQ exist, although they are generally consistent with the overall objective of ensuring safe, reliable output from research and development and operational activities. The SUBSAFE program, for example, is an entire program amplifying the guidelines of the basic instruction to more specifically address submarine safety. Another program, the Naval reactor propulsion program, contains numerous specific quality assurance directives addressing aspects of quality control and assurance ranging from identifying and controlling materials suitable for reactor plant application to controlling safety in reactor system and subsystem operations and testing.

The operational branches of NAVSEA include the Naval shipyards, Naval ship repair facilities, and the offices providing the liaison between the Navy Department and commercial shipyards and repair activities. The liaison offices include the offices of the Supervisor of Shipbuilding, Conversion and Repair, commonly referred to as SUPSHIP. The Naval Shipyard Commander and the Supervisor of a SUPSHIP organization share the responsibility for completing the construction, repair or overhaul mission with the vessel's commanding officer. Frequently, the Naval Shipyard Commander is also the Supervisor of the SUPSHIP office within his Naval District. The administration of the quality program is assigned to the Quality Assurance Officer of the Naval Shipyard and SUPSHIP organization.

The objectives and functions of a Defense Department contract administration activity such as a SUPSHIP office have several major distinctions from those of a Naval shipyard quality assurance organization. The chief difference is in the administration of quality control and assurance procedures. Commercial contractors performing work for the government are required by contracts to assure compliance with the quality requirements of the specific contract being performed. Certain basic minimum quality program requirements must be met for a private firm to be qualified to perform certain types of government work. For the types of work ordinarily performed under SUPSHIP cognizance, these basic guidelines are required by the Master Ship Construction contract (MSC) or the Master Ship Repair contract (MSR). To be eligible to bid for Navy ship construction or repair work, a signator private firm must continuously comply with the provisions of either the MSC or MSR contract regardless of whether the company is presently performing government contract work. Among these provisions are those addressing quality assurance and control.

The SUPSHIP organization acts as the liaison between the government customer and the commercial supplier in all matters including administering the contract and control for quality. The Quality Assurance Office is guided by two basic documents, which have extensive quality assurance supplements:

a. Ship Acquisition Contract Administration Manual (SACAM) - the governing document for use by SUPSHIP in contracting for the construction of vessels.

b. Ship Repair Contracting Manual (Repair Manual) - the governing document for use by SUPSHIP in contracting for ship repair.

Standard Naval shipyard organization for assurance of quality is specified in NAVSEA instruction 5450.14, the Standard Naval Shipyard Organization Manual. Any deviation must be approved by the Naval Sea Systems Command. Besides outlining the organizational structure of Naval shipyards, this organization also describes the duties and responsibilities of staff within the organization.

Using excerpts from NAVSEA Instruction 5450.14, the following subsections briefly discuss the duties and relationships of typical shipyard organizations. First, however, several key observations must be explained to adequately understand how the AOQ function actually works within the Naval shipyard.

- There are parallel, complementary, organizations within the shipyard for non-nuclear and nuclear matters.

- A DOE representative called "Naval Reactors Division of Naval Reactors Representative" is assigned to every Naval shipyard that performs nuclear reactor plant work. This representative reports to the Director, Division of Naval Reactors, U.S. DOE, and provides the Shipyard Commander with an independent review and surveillance of all shipyard work relating to Naval nuclear propulsion matters. The Representative has free access to all elements of the shipyard dealing directly or indirectly with Naval nuclear propulsion. The review and surveillance is not intended to detract from, change or diminish the existing responsibility of the Nuclear Engineering Manager or any other shipyard official. The Naval Reactors Representative is provided suitable and sufficient office space in the shipyard and other administrative support to carry out the assigned function.

- The USN puts the burden of proof for assurance of quality totally on the contractor. USN inspections, while extensive and involving both shipyard and ship's force review, do not substitute for a contractor inspection, and the use by the contractor of independent auditors is encouraged. The intent is to allow the USN inspectors to selectively review phases of the overall program rather than become immeshed in minute details of specific technical areas.

- The USN shipbuilding program requires readiness reviews at the shipyard project level involving ship's force, shipyard departments, contractors, and quality assurance staff at both periodic (e.g., weekly) intervals and workphase points (e.g., pre-hydrostatic testing) (NAVSEA Instruction 5450.14).

- USN shipyard organizational structures have been mandated to ensure that the QA manager and the onsite Naval reactors representative have direct access and responsibility for reporting to senior shipyard management and their respective directorates at Naval Sea Systems Command headquarters.

- A prioritization effort has been made in the USN program to base quality requirements on and to direct audits to the equipment, systems, and/or material which are most critical. A formal mechanism is established for classifying or prioritizing quality efforts to ensure that attention regarding assurance of quality is not placed only on what just happened ("squeaky wheel" syndrome). An important distinction is made, however, that while the range and depth of requirements may change depending on the importance of the component or system, no adjustment is made in the degree of compliance (i.e., requirements must be met).

- The USN has issued strong guidance for detecting and preventing deliberate malpractice and fraud related to construction assurance of quality programs (NAVSEA 1976).

- Careful attention has been taken to ensure that onsite inspectors are not overloaded with administrative responsibilities (i.e., duties are prioritized) such that they do no have the freedom or time to examine problem areas as they arise.

- The USN has established a program to evaluate the quality of contractor products and maintains a computerized data bank of vendor record and component performance information, accessible to both USN and commercial staff. The vendor and component information collected in this data bank is analyzed to identify and track potential items of concern. These analyses have been characterized to look for "warning signs" or other indicators to key inspection staff on aspects or features of assurance of quality programs that need to be monitored in closer detail.

In the Naval shipyard, there are seven individuals whose functions directly encompass the assurance of quality. Their responsibilities for implementation of the quality programs are discussed below.

- Nuclear Engineering Manager. The Nuclear Engineering Manager is responsible to the Shipyard Commander for resolving all nuclear reactor plant technical matters. These responsibilities include the following:

  - testing nuclear reactor plants and integrated propulsion plants on nuclear powered ships

  - advising responsible shipyard officials on quality control and radiological controls of such work, including special fabrication procedures, instructions, proper manning levels, erection and overhaul schedules and sequences, estimates, facilities, and industrial safety and security

  - quality control engineering of nuclear reactor plant work.

- Head, Nuclear Quality Engineering Division. The Head of the Nuclear Quality Engineering Division is responsible during the construction, overhaul, testing, maintenance and refueling of Naval reactor plants for the following:

  - establishing or causing to be established quality control procedures to be used for nuclear reactor plant work

  - analyzing and assessing the quality of reactor plant work; recommending remedial actions to correct and prevent recurrence of errors in workmanship and procedures

- providing information feedback to NAVSEA for improving specifications

- conducting irregular periodic audits of shipyard operations related to nuclear reactor plant quality control matters

- performing the responsibilities of the "governmental inspector" for reactor plant work, as defined in applicable NAVSEA standards.

- Production Officer. The production department, headed by the Production Officer, plans, schedules, and supervises all new ship construction work.

- Nuclear Production Manager. The Production Officer's nuclear area supervisor is the Nuclear Production Manager, who also has direct access to the Shipyard Commander. Duties include the following:

  - exercising line authority as a deputy to the Production Officer for the nuclear aspects of new construction, overhaul, testing, refueling and core loading of concern to the Production Department

  - assuring that all nuclear production work is accomplished on time, at reasonable cost, and in accordance with specified technical requirements and good workmanship standards

  assuring that lists of production personnel qualified for nuclear work are maintained and concurring in such lists.

- Quality Assurance Officer. The Quality Assurance Officer reports directly to the Shipyard Commander and is responsible for the following:

  - planning, executing and monitoring a quality assurance program for the shipyard in accordance with applicable quality-assurance criteria and with due consideration to the safety of ships, equipment and personnel

  - planning and managing a quality-cost measurement program for the shipyard (prevention, appraisal and failure costs)

  - providing guidance, integration, and evaluation of the efforts of the shipyard toward the prevention of product quality degradation

  - investigating and evaluating quality problems to determine the fundamental cause, cost, scope, and significance of the problems

  - directing a shipyard program to ensure calibration of measuring and testing equipment; maintaining measurement standards and performing calibration

- developing a quality assurance training program for the shipyard

- performing quality assurance functions such as inspection, physical and chemical testing, qualification testing, non-destructive testing; witnessing formal operational tests, as assigned; performing audits of the procedures, conduct, and records of inspections; and performing tests of weight-handling equipment

- making failure mode analyses and process capability studies

- establishing technical requirements for metal fabrication and thermal joining processes

- managing to the shipyard quality assurance audit program, and performing internal audits to determine shipyard compliance with quality requirements

- executing such research, development, test and evaluation programs as are assigned.

• Chief Quality Assurance Engineer. The Chief Quality Assurance Engineer reports to the Quality Assurance Officers. Responsibilities include performing and coordinating all activities of the Quality Assurance Office, with the exception of those functions performed by the Nuclear Quality Assurance Manager.

• Nuclear Quality Assurance Manager. The Nuclear Quality Assurance Manager exercises line authority as a deputy to the Quality Assurance Officer for the nuclear quality assurance of new construction, overhaul, testing, refueling and core loading of Naval reactor plants. The Nuclear Quality Assurance Manager has direct access to the Shipyard Commander, and is responsible for the following:

  - confirming that nuclear work is performed to specifications and procedures and recording required data to document that the work is performed correctly, including maintenance of documentation files

  - informing the appropriate department heads and the Shipyard Commander of work not being performed to specified requirements or not in accordance with safety practices

  - assuring that adequate planning and scheduling are provided for the nuclear work performed under the responsibility of the Quality Assurance Officer, including assuring that adequate manpower resources and equipment are provided within the Quality Assurance Office to prepare for and perform reactor plant work

- keeping informed of the nuclear work performed under the cognizance of the Chief Quality Assurance Engineer and assuring that the Quality Assurance Officer and the Shipyard Commander are advised of work not performed to required standards

- assuring that lists of Quality Assurance Office personnel qualified for nuclear work are maintained and concurring in such lists

- consistent with the above, seeing that all functions of the Quality Assurance Office concerned with nuclear work are accomplished on time and at reasonable cost.

D.4.4.2 U.S. Commercial Shipbuilding AOQ Program

In areas of complexity, potential for hazard to the general public, and strong governmental involvement, the U.S. merchant marine shipbuilding program can be related to the U.S. commercial nuclear power plant construction program. Vessels include supertankers, combined ore/bulk/oil (OBO) carriers, and liquefied natural gas (LNG) carriers, in addition to containerships, barge carriers and roll-on/roll-off van carriers (Maritime Administration 1982). Because these ships are so large, so complex, and in many cases carry hazardous cargos, assurance of quality in construction is essential.

Background. Private shipyards in the United States employ approximately 175,000 people, about two-thirds of whom are concentrated at 26 major shipyards involved in constructing naval ships and/or major ocean-going or Great Lakes merchant ships (Maritime Administration 1982). The deep-draft merchant vessels being constructed represent the largest and most complex mobile structures manufactured. Their assembly involves nearly every kind of material, draws on the products of almost every industry, employs almost every skill, and is intended to achieve a thirty-year life, which is comparable to that of a commercial nuclear facility. Many of the ships being constructed represent advanced designs that are equivalent to three to five of the older ships that they replace.

Governmental regulatory bodies are involved in the assurance of quality for U.S. merchant vessels for two major reasons:

- concern for the substantial hazard to life and property from commercial vessels in the case of an accident

- involvement of the U.S. Government in Construction Differential Subsidy (CDS).[a] (Although this was applicable to the program studied, the subsidy has reportedly been discontinued except for contracts existing in 1982.)

(a) In 1981 the Maritime Administration (MarAd) awarded CDS contracts to build 83 new merchant ships valued at $4.4 billion; the government's share, including national defense features, was $1.74 billion (Maritime Administration 1982).

AOQ Program Organization and Requirements. The United States Coast Guard (USCG) is responsible for enforcing rules and regulations set down in Title 46 (Shipping) of the Code of Federal Regulations necessary for the safe construction and operation of U.S. flag vessels. The USCG inspects and certifies various tanker, passenger, cargo, and miscellaneous ships prior to their use. The principal legislative authority for these inspection and certification activities are found in 46 CFR 369 and 391. The USCG inspection and certification regulations apply to nearly all large vessels. Smaller vessels may or may not be covered, depending on their size, capacity, and type of power. The USCG Merchant Vessel Inspection Division in the Office of Merchant Marine Safety administers the inspection and certification.

The USCG regulatory structure for each class of vessel is basically similar. Initially, the USCG must approve the plans for a proposed tanker [46 CFR 31.10-5(a)], passenger (46 CFR 71.20-10), or cargo (46 CFR 91.20-5) vessel. When a vessel passes the initial inspection upon completion of construction, the USCG issues a certificate of inspection. Several points relating to assurance of quality in the USCG program are worth noting:

- On a trial trip of each new or converted ship, an inspector is present to observe safe operation (46 CFR 31.10-40).

- It has been conservatively estimated that 9 percent of the total estimated construction costs of a vessel are due to U.S. government regulation. The U.S. government requirements themselves, however, are essentially the same in most cases as internationally recognized standards (Ernst and Whinney 1979, pp. 7-12).

- A survey by Ernst and Whinney in 1979 found that most shipping and shipbuilding companies (>80%) felt that regardless of current regulations, they would continue to perform the same inspections and tests at the same frequency because of their concern for the safety of the crew and ship. Because safety and the assurance of quality were felt to be everyone's concern, including the vessel owner's, mutual understanding and working relationships would be preferred and should be in general more effective than the adversary position that was sometimes felt to exist between the Coast Guard and the industry (Ernst and Whinney 1979, pp. 5-31).

- In the inspection of hulls, boilers, and machinery, the current standards established by the American Bureau of Shipping (ABS) are designated Rules for Building and Classing Steel Vessels. These apply to materials and construction of hulls, boilers, and machinery, except as provided for by other regulations in Title 46, and are accepted as standard by the USCG. The approved plans and certificate of the ABS, or other recognized classification societies for classed vessels, may be accepted by the USCG as evidence of the structural integrity of the hull and the reliability of vessels, except as otherwise specified in 46 CFR 31.10-1.

- Since May 1965, the ABS has been designated as an organization duly authorized to issue the "Cargo Ship Safety Construction Certificate" to certain cargo ships on behalf of the United States of America as provided in the regulations. At the option of the owner or agent of a vessel and on direct application to the ABS, the ABS may issue to a vessel a Cargo Ship Safety Construction Certificate having a period of validity of not more than five years. If the ABS determines that a vessel that was issued a Cargo Ship Safety Construction Certificate no longer complies with the ABS's applicable classification requirements, it will immediately furnish the USCG with all the relevant information to determine whether the USCG will withdraw, revoke or suspend the certificate (46 CFR 91.60-45).

- Before any construction or conversion is started on a vessel, application for the approval of contract plants and specifications and for a certificate of inspection is made in writing to the USCG, and construction or conversion cannot proceed until approval is granted (46 CFR 31.01-20).

- Triplicate copies of contract plans and specifications are forwarded to the Officer in Charge, Marine Inspection, in whose district the construction will take place, for submission to headquarters for approval. However, if the vessel is to be classed, such plans and specifications shall first be approved by a recognized classification society. If the plans and specifications are adequate, they are approved. During construction and upon completion of construction, each vessel is inspected by the Officer in Charge, Marine Inspection, to determine whether it has been built in accordance with the approved plans and specifications (46 CFR 31.10-5).

AOQ Program Implementation. This section discusses the roles of the MarAd, the ABS, the Ship Structure Committee and their interactions with the USCG. However, before discussing the roles of each of these organizations, the following are noted as significant factors in the assurance of quality for the commercial shipbuilding program.

1. A cooperative relationship has been fostered between the builders, buyers, regulators, and standards-setting groups. An emphasis has been placed by the interested parties on maintaining cohesiveness rather than retaining individual freedoms. Involvement of the federal government with industry through the active participation of staff members on standards and codes committees and Memorandums of Understanding has been successful.

2. Both ABS and USCG have a corps of Inspectors/Surveyors adept at shipbuilding practices and interpretation and enforcement of their respective rules. The autonomy of these Inspectors/Surveyors is generally accepted by U.S. shipbuilders without the adversary relationship so common in other programs. The reason for this acceptance, as outlined by Lisanby and Hass (1981), lies in the commercial impact, since denial of certification is accepted by the courts as proof of failure on the part of the shipbuilder so that the commercial loss of the customer can be shifted to the shipbuilder.

3. Standardization of ship design is a major industry policy, which has greatly simplified assurance of quality.

• Maritime Administration. The MarAd, an agency of the U.S. Department of Transportation since August 6, 1981, administers federal programs designed to promote and maintain a merchant marine capable of meeting America's requirements for both commercial trade and national defense. From 1950 to 1981, MarAd was part of the Commerce Department.

The MarAd is indirectly involved in assurance of quality, and is mainly an economic and contractual, not a technical, organization whose purpose is to ensure that subsidies (where applied) are not misspent. To accomplish this, it has established policies and procedures for the conduct of subsidy condition surveys (46 CFR 272.2-5). Besides requiring and specifying the extent of surveys necessary to validate subsidies, the MarAd also is involved in developing guidance to assist the maritime industry and in preparing detailed ship specifications. The MarAd's Standard Specifications for Merchant Ship Construction (PB-290,400; January 1979) requires that the contractor submit working plans within 60 days after the award of the contract, including schedules for readiness reviews. These plans identify which reviews are required, who will participate, and what will be reviewed, including change orders. Finally, the MarAd is involved in promoting the U.S. maritime industry through its research and development programs.

• American Bureau of Shipping. The American Bureau of Shipping (ABS) is a nonprofit, nongovernmental ship classification society that establishes and administers standards (which it refers to as Rules) for the design, construction and periodic surveillance of merchant ships and other marine structures. Members of the society include naval architects, marine underwriters, shipowners, shipbuilders, and governmental representatives (including U.S. Department of the Navy, U.S. Coast Guard, and U.S. Maritime Administration). The ABS acts as a self-regulatory agency to the maritime industry, not just in the United States, but in over 90 countries.

The ABS's charter is to continually work to develop and update its rules through a pyramidal committee structure that comprises 19 technical committees and panels, whose members serve without compensation to ensure impartiality. Rule changes are initiated at the special committee or panel level, or by someone in the maritime field. If a special committee (e.g., Materials, Electrical Engineering, Nuclear Applications, Welding, or Operations) recommends that a rule be adopted or changed, such a proposal (depending on application) is forwarded to one of two full committees (Engineering or Naval Architecture).

This second committee will arbitrate whether such action should be taken, then submit their recommendation to the technical committee, which has the final say on each proposal's acceptability. These rules are published in an array of documents that apply to ship construction. The basic implementing document for most major ship construction is Rules for Building and Classing Steel Vessels, which is annually updated. This document is called out in 46 CFR 31.10-1 regarding required USCG inspections accepted as standard by the Coast Guard, except as appropriately noted in the regulations.

The following excerpt from the ABS description of classification describes how the rules are administered:

> The formal classification procedure begins when an official request for the classification of a ship or marine structure is voluntarily submitted to ABS. This usually results from an owner specifying a desire for ABS classification to the shipyard whereupon the shipyard contracts for classification serves with ABS.
>
> The vessel design is then submitted to ABS for verification that the plans conform to accept standards of good practice for vessel design embodied in the 'ABS Rules for Building and Classing Steel Vessels,' or other various ABS Rules listed earlier. So, in reviewing a given set of design plans, ABS is comparing them with a compendium of experience factors and proven scientific principles. In this way, ABS is able to determine whether the design is adequate in its structural and mechanical concept and, therefore, acceptable to be translated into an actual vessel.
>
> To conduct the plan review function, the classification society employs technical staff surveyors trained in the skills of naval architecture, marine engineering, and other associated disciplines. These specialists scrutinize the vessel's design to confirm that the details comply with the standards set forth in the published Rules. Their review may also include sophisticated analytical procedures employing one of the many ABS computer programs. If the design is found to be not in compliance with the Rules, ABS amends the plans or notifies the owner or designer of the departures from the Rule requirements. During the entire review process, ABS is available for consultations with the owner and designer.
>
> After a design has been reviewed by ABS technical surveyors and found to be in conformance with the Rules, ABS field surveyors, who are experienced in the construction of hulls and fabrication of machinery and components, 'live with the vessel' at the shipyard from keel laying to delivery. In so doing, they survey construction to verify that the plans are followed, workmanship is of the best quality, and the Rules are adhered to in all respects. Field surveyors also witness testing of material, machinery, and components at manufacturers' plants and fabricators' shops to determine that they also comply with the Rules. During the entire time of construction, ABS maintains an ongoing dialogue with the owner and shipyard to make sure the Rules are understood and adhered to and also to assist in resolving any differences that may arise.
>
> When completed, a vessel undergoes sea trials and an ABS field surveyor attends the trials to verify that the vessel performs according to the requirements as specified in the Rules. In order for a vessel to be formally classed, a report must be presented to the ABS Classification Committee. This Committee, composed of prominent

individuals from the maritime industry who serve without compensation, meets twice a month to perform a final review of the vessel's 'credentials.' A vessel found to be acceptable in all respects according to the Rules is then granted ABS classification by that Committee and issued an official ABS classification certificate. In granting class the Committee is saying, in essence, that the vessel is in conformance with the ABS Rules and to that extent is mechanically and structurally fit for its intended service.

An additional item of some importance concerning the ABS involves a Memorandum of Understanding (MOU) signed by the ABS and the USCG in early 1982. As stated in the 1982 ABS annual report, page 3:

> One memorandum provides for Coast Guard acceptance of ABS admeasurement and tonnage certification of all U.S. flag vessels. The other, known as MOU II, is an expansion of an earlier Memorandum, known as MOU I, signed in June of 1981, and provides for Coast Guard acceptance of ABS plan review and inspection of various hull and machinery items for new construction of U.S. flag vessels built to the classification requirements of the Coast Guard.
>
> In this regard, it was written into the memorandum that an orderly and deliberate transition will be assured through a phasing-in-process, thereby allowing ABS to augment its resources as necessary and appropriate.

- Ship Structure Committee. To integrate research on marine transportation, a committee involving most of the major participants was formed. As stated by the Booz-Allen Study (1981), the mandate of the interagency Ship Structure Committee (SSC) is to conduct an aggressive research program. This program's objective is, in the light of changing technology in marine transportation, to improve the design, materials and construction of the hull structure of ships and other marine structures by extending knowledge in these fields. Its ultimate purpose is to increase the safe and economic operation of all marine structures. The SSC is composed of one senior official each from the USCG, Naval Sea Systems Command, Military Sealift Command, MarAd, and the ABS. In 1977, the U.S. Geological Survey, which is responsible for the personnel, safety and environmental aspects associated with the offshore oil and mining industry, agreed to participate.

The SSC formulates policy, approves program plans, and directs funds from its member agencies into the research program. Four representatives from different divisions within each agency meet periodically as a Ship Structure Subcommittee to ensure achievement of the program goals and to evaluate the results in terms of ship structural design, construction and operation.

D.4.5 NRC Assurance of Quality (AOQ) Program

This description of the NRC's program for assuring quality in the design and construction of nuclear power plants has been developed by reviewing the available literature and by conducting interviews with NRC staff both at the headquarters of the Inspection and Enforcement Office and at regional offices in Atlanta, Georgia; Arlington, Texas; and Walnut Creek, California. The purpose of this review is to provide a basis for evaluating the transferability of AOQ program features and practices from other industries and agencies to the NRC and the industries involved in building nuclear power plants.

D.4.5.1 Background

The nuclear industry originated with the U.S. Army Engineers' Manhattan District Project in World War II. Shortly after the end of the war, a new government agency, the Atomic Energy Commission (AEC), was formed and the nuclear industry, which at that time involved only the federal government and its contractors, was transferred from the military to the AEC. The expansion into commercial applications by the private sector became possible with the passage of the Atomic Energy Act of 1954. A separate arm of the AEC was established to regulate the private sector in these commercial applications.

The Energy Reorganization Act of 1974 further separated the regulatory function from nuclear energy promotion by forming the Nuclear Regulatory Commission (NRC). This legislation also created the Energy Research and Development Administration (ERDA) to encourage and promote the commercial applications of nuclear energy, with the NRC responsible for the regulatory functions.

Although a few new corporate organizations dedicated to activities in the nuclear field came into being, the major thrust of the commercial industry was carried by existing corporate organizations. These organizations were primarily the electrical utilities, power plant designers (the architect-engineer firms), and their traditional suppliers of central station power plant equipment. The major corporations involved have tended to establish separate divisions or components directed to this new and evolving market place. In general, however, major corporations dedicated primarily to commercial applications of nuclear energy have not evolved in the United States.

The regulatory challenge to the NRC and its predecessor, the AEC, has been formidable. Nuclear technology has evolved very rapidly. In its short history, less than 30 years, the regulatory program and organization have experienced their own evolutionary processes while simultaneously regulating the "nuclear industry." This industry, however, has never existed as an entity in the traditional sense such as the iron and steel industry, the automobile industry or the aircraft industry. By contrast, the "nuclear industry" exists as an offshoot, almost a sideline, of several older, well-established industries, i.e., the utilities, the architect-engineers and the power plant equipment manufacturers. These industries had long been regulated to some extent by codes and standards, public utility commissions, etc. However, the depth and breadth of the NRC regulatory program certainly presented a major change from traditional business and working environments. In essence, fully mature business enterprises with long, well-established methods of operating had to make major (in some cases nearly revolutionary) changes in order to participate in what appeared to be a growing market area. Some of these organizations have made the necessary adjustments much more readily than others. Implementing and maintaining an effective and consistent regulatory program throughout the U.S. under these institutional circumstances has been difficult. This regulatory situation appears much more difficult than, for example, regulation of the aircraft industry, in which the private sector and the regulatory process evolved in parallel. In the latter situation, corporate business traditions and practices evolved much more in concert with the government's regulatory program.

D.4.5.2 Organization and Responsibilities

When the NRC was formed in 1975, the major organizational components were Reactor Licensing, Fuels and Materials Licensing, Inspection and Enforcement, Regulatory Research, and Standards Development. The inspection and enforcement arm included a staff at NRC headquarters and five regional offices.

Criteria for licensee QA programs were developed by the Office of Standards Development. The review of licensees' proposed QA programs was in the licensing components of the Office of Reactor Licensing, and the Office of Inspection and Enforcement was responsible for ensuring that licensees carried out their commitments as approved by NRC licensing and presented in the Safety Analysis Report. The NRC's QA efforts for nuclear power plant construction, therefore, were distributed among the three major organizational divisions.

In 1981, the regional offices were separated from the headquarters Office of Inspection and Enforcement and began reporting directly to the NRC's Executive Director for Operations. In 1982 and 1983, the NRC's headquarters staff was reorganized (in a series of actions), and all QA efforts were assigned to the Office of Inspection and Enforcement. Most of the NRC staff members interviewed felt that this was a very positive step; centralizing QA activities provided a mechanism to expedite the resolution of any differences or disagreements among the various functions within the NRC. The organizational chart for the NRC staff as of January 1, 1983, is shown in Figure D.4.

The headquarters Office of Inspection and Enforcement is now responsible for developing criteria and standards for licensee QA programs, for reviewing licensee QA programs, for licensing (QA issues) and establishing policies, and for defining the program for inspecting licensees by the regional offices to assure that the licensees' programs are carried out. It is responsible for managing major enforcement actions through orders and civil penalties. Further, it recently took on the added responsibility of inspecting and evaluating vendors, designers and suppliers wherever they may be located.

The five regional offices (see Figure D.4) are responsible for executing the established NRC policies and assigned programs relating to inspection and enforcement within their regional boundaries. The regional administrators have the authority to stop any or all safety-related work during the construction and/or operation of nuclear power plants.

In general, the regional offices conduct an inspection program that has been basically defined by the headquarters Office of Inspection and Enforcement. However, the regional offices administratively report directly to the Executive Director for Operations as does the headquarters Office of Inspection and Enforcement.

Since the licenses are issued to the utilities to construct nuclear power plants, the utility is held totally responsible by the NRC. If an enforcement action concerning a construction contractor is deemed appropriate, the action is taken with the utility, not directly with the contractor.

NRC's Relations with Others. The NRC has placed a resident inspector at each of the nuclear power plants under construction. The inspector's efforts are supplemented by periodic visits to the site by regional-office-based inspectors who generally look at specialty areas. The total level of effort is estimated to average about 1-1/2 persons for each reactor unit under construction.

Resident inspectors are provided office space at the site and have ready access to all documents, records and files pertaining to the assurance of quality and the licensee's commitments on quality. The NRC inspectors also observe the work in progress. The basis for their authority, in general, is to assure that the licensee fulfills the commitments made during the licensing process.

The NRC operates with a very high degree of public visibility. For example, individual inspection reports become public information, and extensive public participation occurs in the licensing process, including the various hearings that are conducted. Direct public access to NRC inspectors is provided and encourged.

Resources. As noted earlier, the actual NRC inspection effort for each reactor unit under construction averages the equivalent of about 1-1/2 full-time persons. Nearly all of the inspection staff is made up of engineers. Special multi-week training programs on technical aspects of the inspection job are provided by the NRC, with a one-week course on the fundamentals of inspection.

This normal level of inspection effort is supplemented in some cases by construction assessment teams (CATs) from NRC Office of Inspection and Enforcement staff supplemented by contractor or consultant experts. These teams perform three to four detailed inspection efforts per year. Each inspection covers a four- to six-week period. A typical effort by a CAT amounts to about 14,000 man-hours per inspection.

The staffs of some regional offices were concerned with maintaining high levels of proficiency and adequate numbers of persons in inspection, a concern attributed to competing with industrial organizations for experienced people.

The NRC regional offices each have one or two mobile vans with nondestructive testing capability. The vans can be moved from site to site, which provides some capability to perform independent nondestructive examinations in special cases, generally at sites with major problems. This effort is supplemented by the use of contractors to assist in conducting independent examinations--both nondestructive and destructive.

ORGANIZATION CHART

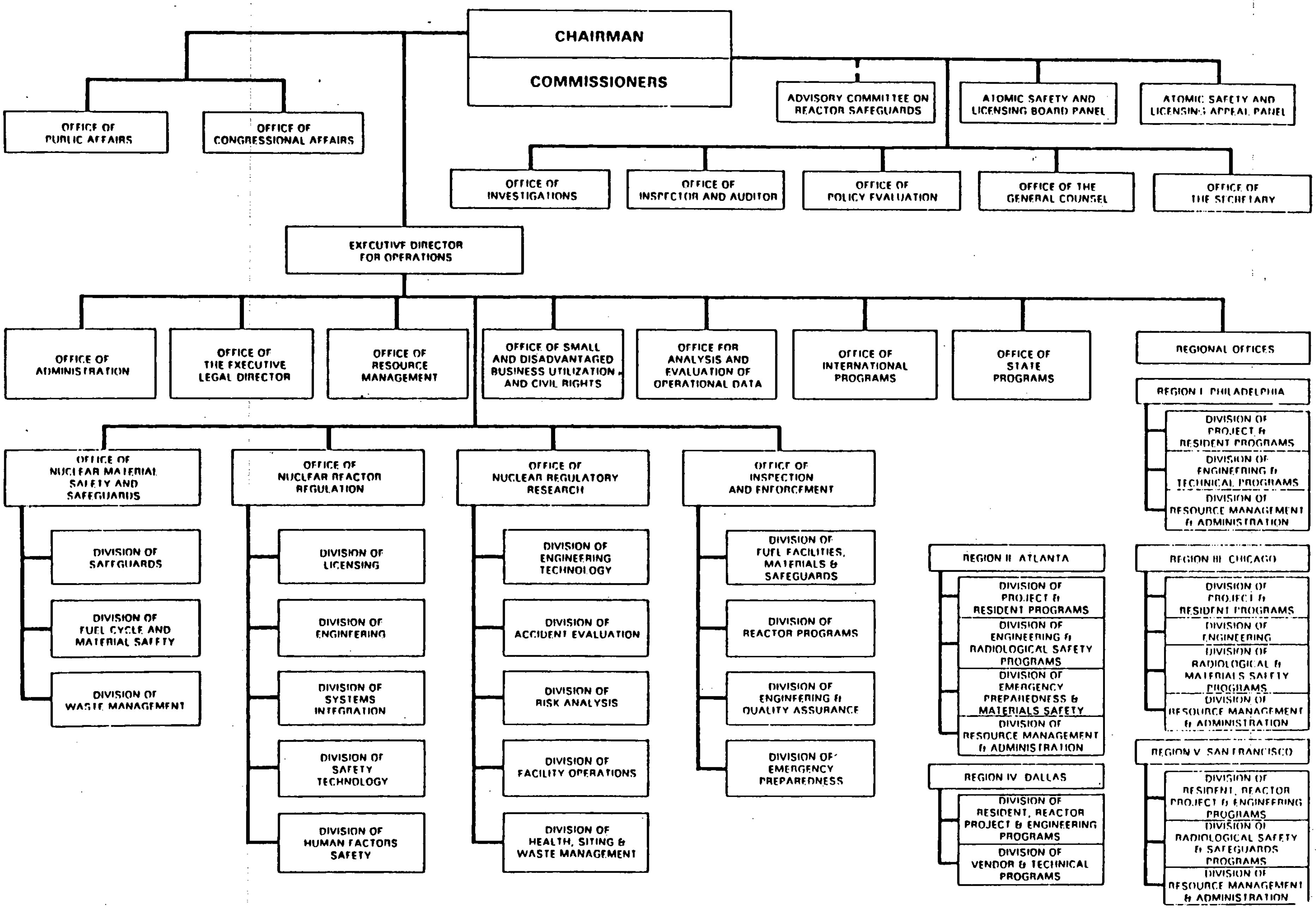

FIGURE D.4. U.S. Nuclear Regulatory Commission

D.4.5.3 AOQ Program

The major thrust of the NRC's program to assure quality construction of nuclear power plants is directed to the owners/operators of the plants. The utilities that operate the plants include a government-owned corporation (TVA), local government agencies (i.e., public utility districts, cooperatives) and privately owned corporations. In any case, the utility must obtain a permit from the NRC to construct a nuclear power plant. The application for such a permit includes all of the information necessary to analyze safety, siting and environmental issues, and the licensee's program for quality assurance. The QA program for safety-related systems and equipment must meet the requirements of the NRC's QA criteria contained in 10 CFR 50 Appendix B, which is the basis for the NRC's program for quality assurance.

The NRC's Standard Review Plan describes the NRC review of a license application for construction. Chapter 17.1 of the Standard Review Plan outlines in considerable detail the requirements that a licensee must meet in applying for a permit to construct a nuclear power plant. In essence, this requires a description of the QA program that the licensee will implement throughout the design and construction of the plant. This program description becomes the basic commitment by the licensee and is therefore the basis for all following QA inspection efforts.

In addition to the program description, the regional office inspection staff will review the licensee's QA manual and the detailed procedures that are to be applied to the project. The results of this inspection are fed into the application review process.

The inspection program carried out by the five regional offices is in accordance with the Inspection and Enforcement Manual issued by NRC's Office of Inspection and Enforcement. The manual includes many comprehensive and detailed Inspection Modules, ranging from "predocketing" inspection of the licensee's QA manual and procedures to the details of inspecting specific equipment, system and component areas. The modules indicate a minimum frequency for inspections, describe what to look for, and provide checklists of what to look at. They also describe acceptable practices for work in progress. The major thrust of these inspection efforts is to review the documentation and the work being done on a sampling basis to determine if the licensee's program is being carried out effectively and in accordance with license commitments.

The NRC's inspection efforts may result in "deviations," or "violations." A "violation" means that a non-compliance with requirements has been identified. A "deviation" identifies a departure from acceptable, standard practices. The licensee must formally respond to non-compliances by identifying what is being or has been done to correct the item noted and what actions are planned or have been implemented to preclude any further similar occurrences. These required responses are to some extent viewed by the licensees as a form of enforcement penalty because of the resources required to prepare the necessary responses. The corrective actions required may also represent new and unplanned efforts and activities for the licensee and/or its contractors.

In more extreme cases, including those where corrective actions have been ineffective or not adequately implemented so that the problems have continued, or where so many difficulties arose that a major breakdown in the licensee's program has occurred, the Regional Administrator has the authority to stop work. Work cannot be resumed until the regional office has been satisfied that appropriate changes have taken place and there is reasonable assurance that requirements will be met.

Another task force type of effort provided by NRC headquarters is identified as the Integrated Design Inspection (IDI). This is generally done in cases identified as near-term operating license situations. The IDI consists of a detailed review of a sampling of the plant's design. The results of these inspections are incorporated into the review process in preparing for the issuance of an operating license.

NRC regional offices also perform, annually, a Systematic Assessment of Licensee Performance (SALP) for each construction plant site. This is an overall assessment of performance.

In some cases, a regional office forms a task force to conduct a detailed construction assessment effort of selected systems or features at a site to supplement the normal inspection activities.

Incorporated in the inspection effort is a review of the qualifications and certifications of the quality assurance/quality control personnel of the licensee and its contractors to assure that these staffs are properly qualified. The NRC provides technical training of its own inspectors with required minimum grades on written examinations. Annual performance appraisals of NRC inspectors are developed and provided.

In essence, the major focus of NRC's inspection efforts is to assure that the licensee is conducting effective QA and QC programs in accordance with the requirements of Appendix B to 10 CFR 50. This effort consists both of reviewing documentation and procedures and of observing work in progress for a review of the actual implementation of the committed program. The NRC inspection effort itself cannot assure that all design requirements are met in the resulting hardware. The inspecting of hardware and observing of construction work in progress are parts of the NRC's effort to assure that the licensee's QA process is functioning properly.

The NRC AOQ requirements permit the licensee to take a wide variety of approaches in its QA program. One of the major variables is the degree of delegation permitted by the licensee to its contractors. However, the licensee is required to maintain a minimal level of QA activities with ready access to the appropriate high levels of management in the licensee organization. Within this framework, some licensees have chosen to delegate quality control inspections with supplementary QA activities to their construction contractors or construction management contractor. Others have chosen to exercise all of these functions under their own direct management control with, perhaps, supplementary staff provided by a contractor.

All AOQ programs must conform to the criteria in 10 CFR 50, Appendix B. This requires extensive documentation of the program, its procedures, resulting records, and the management and control of the documentation for all activities in plant construction. Independent periodic reviews and audits have become a matter of standard practice and are required as is certification of certain QA and QC staff personnel.

D.4.6 Foreign Nuclear Assurance of Quality (AOQ) Programs

Summary descriptions of the AOQ regulatory programs for nuclear power plant construction in six other countries are presented in this section. The six programs studies are Canada, the Federal Republic of Germany, France, Japan, Sweden and the United Kingdom. The summary descriptions were developed almost exclusively from available literature. Time restraints precluded the NRC staff from forwarding the summary description to the six foreign countries for their review, comment, and correction. As a result, inaccuracies may exist in these summaries. If warranted, corrections to these summaries will be made in future revisions or supplements to this report.

The major efforts on these studies were provided by the NUS Corporation, Gaithersburg, Maryland, and Battelle Institute e.V., Frankfurt, Germany. In their studies of Canada, United Kingdom and Japan, NUS provided the advantages of a staff member in residence in England, a staff member previously employed in the Canadian nuclear program, and staff of their Japanese subsidiary (JANUS). The Battelle Frankfurt Laboratory, in studying Germany, France and Sweden, provided the benefits of their extensive research work in nuclear matters pertaining to the European community. Since the studies were conducted primarily by reviewing the available literature, these organizations were particularly helpful in overcoming the language barriers.

Since both NUS and Battelle have well-established relationships with the nuclear industry sectors in various countries, it was possible for them to supplement the literature review with a few discussions with non-government individuals. The information available on Sweden and Japan was also supplemented with data obtained by a representative of N.C. Kist and Associates whose visit to those countries coincided with the studies.

There are significant differences in the programs of the countries studies, however, there are also common elements. Some of the commonalities are:

- Each has utilized the U.S. NRC's QA criteria, 10 CFR 50, Appendix B, in developing its program.
- Each has utilized the International Atomic Energy Agency (IAEA) established Codes of Practice and Safety Guides for nuclear power plants.
- Each has incorporated the government regulatory functions for nuclear power plants into agencies or departments with cognizance over non-nuclear industries and activities not related to radioactive materials or devices.

The program in each country is discussed in the following subsections.

D.4.6.1 Canada

The Canadian nuclear power program has been producing electricity since 1962. Canada has 14 operating reactors with 7,278 MWe capacity and 10 reactors under construction, for a capacity of 14,469 MWe projected for operation in 1990. Currently, nuclear power plants produce 9.7% of Canada's electricity. The annual load factors are among the highest in the world and have been improving. The high annual load factor (77.1% in 1982) is partially the result of the CANDU pressurized heavy water reactors' being refueled while operating. Canada is currently building reactors with capacities of 516 MWe, 756 MWe and 881 MWe. Generally, four reactors of a given size and type are built at a site.

Organization. The Atomic Energy Control Board (AECB) was created in 1946 to implement and administer the Atomic Energy Control Act of 1946 (amended in 1954). This act, in conjunction with the 1974 Atomic Energy Control Regulations (amended in 1978 and 1979) and the Nuclear Liability Act, governs all nuclear activities in Canada. The AECB reports to the Minister of Energy, Mines and Resources and is composed of five members with a staff of 250 people. The AECB has not issued formal QA regulations for generic nuclear power plants. QA requirements have been imposed as part of the licensing activity for each plant. The AECB staff was reorganized in 1978 with the formation of a Quality Assurance and Standards Division. Formal QA regulations and guidance are being prepared. The AECB power reactor safety criteria and principles are defined in "Licensing and Safety of Nuclear Power Plants in Canada" (AECB 1982).

The licensing process in Canada is the responsibility of the AECB, but because of provincial concerns, the AECB has evolved a "joint regulatory process" that enables all concerned federal and provincial agencies and ministries to participate. The AECB acts as the lead agency. However, the provincial government can veto the proposed construction of a nuclear facility within its borders. A veto only applies to a reactor site, not to an evaluation of plant operation and safety. Additionally, provincial government agencies perform reviews and inspection of pressure-retaining components to verify conformance with ASME and Canadian Pressure Vessel Codes.

Subsequent to site acceptance, application for a construction license is made. Primary documentation supporting the application consists of a Preliminary Safety Report (which includes site characteristics, design description, and preliminary safety analyses), a Quality Assurance Program, and preliminary plans for generation (including staffing and training plants). The AECB staff reviews the supporting documents and, if satisfied, recommends to the Board the issuance of a construction license. This review normally includes consultations with the provincial authorities, the applicant, and the applicants' agents to obtain additional information that may be required.

As construction progresses, the AECB staff meets with the applicant and resolves safety-related problems as they arise. During construction, authorization for acquiring and loading heavy water and fuel is issued by the AECB.

Quality Program Requirements. While formal regulations are still being developed, the AECB has supported the development of national QA standards. The Canadian Nuclear Association (CNA) has issued, under authority of the Canadian Standards Association (CSA), a series of standards for nuclear power plants, with N286 being specific to quality assurance. The standard for quality assurance in manufacturing was developed by the CNA as a general standard, CSA-Z299, since the utilities wanted to use it for conventional as well as nuclear equipment. In terms of the principles involved, the standards CSA-Z299 and CSA-N286 are similar to the IAEA Code of Practices and its supporting Safety Guides and to 10 CFR 50 Appendix B. The most significant difference is that CSA-Z299 uses a five-step, graded quality standard for component manufacture and installation. Selection of the appropriate quality program standard is based on the sum of a four-level evaluation of six factors (design complexity, design maturity, manufacturing complexity, item or service characteristics, safety and economics). Canada has also developed standards similar to the ASME Codes, which provide criteria specific to Canadian design and construction characteristics.

In its licensing of nuclear power reactors, the AECB sets basic criteria and requires licensees to design, construct, and operate power reactors to meet those criteria. Besides considering single failures, the licensing process includes analysis of such dual-failure accidents as failure of a process system coincident with failure of a safety system; e.g. occurrence of a large LOCA simultaneously with unavailability of the emergency coolant injection system or impairment of the containment system.

Onsite AECB inspectors monitor compliance with license conditions throughout the construction and into the operating stage. A licensee must submit to the AECB an annual report on operation and maintenance of its nuclear power plant. The report includes a numerical assessment of the reliability of safety-related systems during the reporting period.

To ensure that provincial requirements are met by licensees, the AECB and the provinces have developed a joint regulatory process that is operative from the application stage through construction and facility operation. The AECB licensees are inspected periodically to ensure compliance with license conditions. Inspections may be carried out by AECB staff appointed as inspectors, or by provincial officers also appointed as AECB inspectors on agreement with their provincial ministries or departments. Provincial inspectors so nominated are supplied with an AECB inspector card that provides access to nuclear facilities and users' properties. They inspect according to the AECB regulations and report to the AECB as well as to their home office.

With respect to the design of pressure-retaining components, each province where nuclear power plants are to be located has a Pressure Retaining Component (PRC) Safety Department. The provincial PRC Safety Departments exercise general control over pressure vessel or boiler installation in each of the various provinces of Canada. To the extent that these pressure vessels are related to nuclear facility safety and under the AEC Act, the AECB makes use of provincial expertise to perform design examinations, and fabrication, installation and operational inspections. Provinces rely on the AECB for much work that they cannot cover, and there is joint consideration of all major matters.

Quality Program Implementation. Organizationally, Canada may be considered as a single utility for the purposes of comparison to other foreign countries. Twenty-one of Canada's twenty-four plants are owned by Ontario Hydro, two are owned by Hydro-Quebec, and one is owned by the New Brunswick Electric Power Commission. The utilities are similar, with Ontario Hydro dominating nuclear power plant construction. All three utilities are provincial corporations. The AECB holds the utility solely responsible for construction of a nuclear power plant. Given its limited resources, the AECB relies on the technical expertise of the utility and its vendors in implementing construction criteria developed in the license. Most notable is the reliance on utility inspections of suppliers. A system has been developed whereby suppliers' QA is qualified by the utility before a contract is awarded. Ontario Hydro has chosen to drop "Quality Assurance" in favor of "Quality Engineering" (QE). The Quality Engineering Manual was produced in 1975 and issued formally in 1978. Quality Engineering is defined as a planned and systematic application of scientific and technical skills and management activities to achieve the required level of quality and to provide assurance that this is being done effectively and efficiently.

The Quality Engineering Program is administered by Level 3 managers (divisional directors). Specific responsibilities in each of the areas of design, procurement, construction, commissioning and operation are defined consistent with the line responsibilities for engineering activities in each area. The Quality Engineering Department in the Design and Development Division is responsible for providing the secretariat, including necessary staff support, to the Quality Engineering Policy Committee.

The goal of the Quality Engineering Policy Committee is to promote a coordinated approach to quality engineering in the Operations Group and provide to the executive vice-president, Operations, recommendations on QE policies, objectives and strategies for all areas of design, procurement, construction commissioning and operation; to provide advice to the committee chairman with respect to the suitability of the QE procedures (for adherence to policies, support of objectives, etc.); and to keep members mutually informed on QE matters.

For each project, the project engineering and construction departments under a project manager are assembled within the Generation Projects Division. These departments perform the detailed design, procurement and construction processes for that particular project. The project manager is responsible for designing the project to the requirements specified by the Design and Development Division. During this stage, the project manager is responsible for the overall quality engineering program, engineering manager for the part of the program related to quality engineering in design, including procurement, and the construction manager for the part of the program related to QE construction.

Prior to awarding a contract, equipment purchaser must ensure that a supplier can immediately perform in compliance with the relevant QA codes and regulatory requirements, or alternatively, be able to so perform prior to commencement of the work. Ontario Hydro is qualifying suppliers' quality programs either by a formal audit or by an evaluation by inspection. To minimize the number of formal audits being performed, several utilities, consulting engineering firms and regulatory agencies combine to carry out joint audits. CSA has now embarked on a program of qualifying suppliers' programs to the Z229 Standards. A supplier will then be subjected to a periodic audit by CSA.

Product Engineers holds post-award meetings with major suppliers during the life of the contract. Participation at these meetings might include other functions within Ontario Hydro, along with the suppliers' representation from Design, Project Management, Quality Assurance, Purchasing, Manufacturing, Production Control, Contract Administration or Management. The inspector assigned to the contract attends the meeting to provide input from day-to-day surveillance of the contract. The purpose of the meeting is to ensure that the supplier has planned for and carries out all aspects of the contract, including development work, qualifications, submission of manufacturing, welding, nondestructive testing and shipping procedures, and submission of inspection and test plans and history dockets.

D.4.6.2 Federal Republic of Germany

By early 1983, the Federal Republic of Germany (West Germany) had 15 nuclear power reactors in operation, with a total installed capacity of 9,800 MWe. At that time, there were 12 additional units under construction which are expected to add an additional 13,000 MWe installed capacity (Nuclear Engineering International 1983).

Organization. The legal base for QA/QC programs applying to the planning, construction and operation of nuclear power plants in West Germany rests in the Atomic Energy Act (ATG), last revised in 1976. However, the term "QA/QC" is not defined in the ATG. The ATG provides the legal framework for the licensing proceedings for nuclear power plants, details of which are prescribed in the License Procedure Ordinance (AVerfVO). This ordinance states explicitly that the applicant for a license provide a safety report, as well as

> Factual statements enabling the examination of the reliability and expert knowledge of the persons responsible for the erection of the installation and the management and control of its operation, as well as factual statements enabling the examination of the requisite knowledge of all persons working on the installation.

These general requirements provide the basis of all ensuing QA/QC programs imposed by the regulatory authorities.

Nuclear power plants in West Germany are licensed by the individual federal states on behalf of the federal government under the supervision of the Department of the Interior (BMI). With respect to nuclear power plants, the BMI has three major advisory bodies: the Committee for Reactor Safety, the

Committee for Radiological Protection, and the Committee for Nuclear Safety Standards. There is also a State Committee for Nuclear Energy, which in 1982 issued a "standard set of information to be submitted to the licensing authority in the course of licensing proceedings." In 1980, the Committee for Nuclear Safety Standards (KTA) published the General Requirements for QA/QC. These rules have the force of regulations.

Quality Program Requirements. The Committee for Reactor Safety (RSK) is a consulting body set up by the BMI. RSK's findings are limited in that they only have the force of recommendations (to the BMI, and, via BMI's supervisory role, to the state authorities). The actual importance of these findings cannot be overstated, however. The RSK has recommended guidelines for pressurized water reactors ("RSK-Leitlinein fur Druckwasserreaktoren," 3rd edition, October 1981) which constitute the framework of safety-related standards that must be adhered to by an applicant. The RSK Guidelines consolidate a wealth of BMI regulations and KTA rules supplemented by the RSK and its subcommittees. In various instances, the extent, methods, and even specifications of QC test procedures are detailed by the RSK guidelines. The RSK has set for itself the duty of regularly revising and updating the Guidelines to keep them abreast of "the up-to-date scientific and technical knowledge."

The Committee for Radiological Protection (SSK), is an important advisory body to BMI, but has little direct involvement with the AOQ program.

The Committee for Nuclear Safety Standards (KTA) also reports to the BMI. Its task is to establish safety-related standards and to further their adoption in all sectors of nuclear technology. The KTA provides a highly collaborative approach to the development of the rules. Its membership includes representatives from many sources: suppliers, vendors, utilities operating nuclear power plants, Department of Interior, state licensing authorities, expert institutions, other governmental departments, national nuclear laboratories, trade unions, insurance companies and the Commission for Industrial Standards.

In the context of licensing and surveillance of nuclear power plants, TUV (Technische Uberwachungs-Vereine) and GRS (Gesellschaft fur Reaktorsicherheit) organizations are of utmost importance. Historically, the TUV organizations have been set up by industry as self-financing, independent agencies to act as "watch dogs" on technical hazards in and through large industrial plants. They have built an excellent reputation for technical scientific ability and trustworthiness. They inspect and test all kinds of technical installations (pressure vessels, lifting equipment, bridges, motor vehicles, etc.) or materials on behalf of government authorities or act as supervisory or inspecting agencies for industrial customers. Seven of the 11 TUV organizations have established nuclear departments that work exclusively on inspections, controls, and audits of nuclear power plants on behalf of the licensing authorities. The government licensing authorities do not perform significant inspection activities at the construction sites.

TUV organizations, being independent expert institutions, are also called upon frequently by buyers of complex industrial projects to act as auditors/QC agents. This is also the case with regard to various nuclear power plant projects. However, though not explicitly excluded by law, a situation in which one TUV organization would perform duties on behalf of both the licensee and the licensing authority on the same project is avoided as a matter of principle.

The GRS is a semi-governmental, limited corporation (jointly owned by the TUVs, the federal government and two state administrations). It is also active in the field of licensing proceedings, either directly for the authorities or in a supporting role to one of the TUV organizations. Except for questions regarding prevention of human threat (sabotage or terrorist attack), the GRS has little direct involvement with QA/QC matters.

Quality Program Implementation. Light water reactor plants are constructed under a turnkey arrangement, with a single corporation responsible for plant design, procurement, construction-management and construction. This general contractor and the suppliers of parts, material and components are required to establish their own QA/QC procedural systems. These QA/QC procedure systems are considered the vendors' proprietary material and are not published. They are, however, reviewed and approved by the authorities.

The licensing authority holds the licensee, a private sector utility, totally responsible for the nuclear power plant. However, the general contractor is responsible to the utility to conform to all regulatory requirements and provides a warranty for the plant as a "vendor liability."

One characteristic of the regulatory QA/QC system in West Germany is that control measures are predominantly hardware-oriented. There are no "supplier certificates" or "N stamps." The burden of proof for adequate quality of every item rests on the supplier; who must satisfy inspection authorities that standards are met.

The required QC measures apply to all materials, parts, components and systems deemed safety-related through all steps of assembly and erection.

- Pre-construction Audits: Audits of design and specifications according to fixed criteria and standards.

- Inspection and Tests during Production Phase: Materials, production, acceptance tests and functional testing on all assembly phases, documented and certified by authorized inspectors.

- Commissioning: Functional testing and acceptance testing supervised by authorized inspectors who have to release every system for operational (hot) commissioning.

An important aspect of the principal philosophy of liability in the West German nuclear industry is the fact that the (licensing) authorities perform their control duties on behalf of the populace, which in turn can have the administrative courts (three stages of appeal) control every administrative act.

The obligation of general contractors and suppliers of parts, materials or components to establish in-house QA/QC systems is caused by the regulatory requirements, which mandate a QA level satisfying all relevant safety issues; and the warranty issues in context with the vendor's liability. In essence, the regulatory QA/QC system in West Germany can be characterized by three elements:

- Control measures are predominantly object-oriented. There are no "suppliers certificates" or "N" stamps. The burden of proof for adequate quality of every item rests on the supplier, who must satisfy the inspection authorities that standards are met.

- The inspecting and controlling agency is not an administrative (governmental) body; rather, it is the independent institution, TUV, which has a long record in inspecting services in conventional fields and is accepted as highly competent and trustworthy by all interested parties.

- Basic contractual arrangements are supportive to clear-cut responsibilities and facilitate controls: one licensee/applicant, one general contractor who sells the complete plant on a turnkey basis and who bears full vendor's liability.

D.4.6.3 France

As of January 1, 1983, 32 reactor units were in operation in France. Nuclear power accounts for approximately 40% of Frances electrical production in 1981. Also, at the beginning of 1983, there were 25 additional power reactors under construction in France, one of which is a liquid metal fast breeder reactor (NEI 1983).

All of the light water reactor plants are designed and built under a turnkey arrangement with Framatome, a government-owned corporation, for operation by Electricité de France (EDF), the government-owned utility. With few exceptions,[a] the applicant for a construction and operating license of a nuclear power plant in France is EdF. The EdF is the French monopolistic electric utility that is organized and run like a public company, although it is 100% state-owned.

A series of three standard pressurized water reactor plant designs have been developed. The EDF has developed and utilizes an information system to collect information on the operating experience in all of its plants. This information is used as a basis for improvements in designs and in the overall program. The designs are also modified as necessary to meet site-specific needs.

(a) These exceptions include plants jointly owned and operated by EdF and foreign utilities in locations near the French border, and the Phenix and Super-Phenix fast breeder reactors.

Organization. There is no fundamental French law for regulation of nuclear matters in an encompassing way like the U.S. Atomic Energy Act of 1954. When necessary, matters are settled on an ad-hoc basis via legally binding governmental decrees (decrets) that do not require parliamentary support. Thus, the construction permit for an individual plant is granted by a special decree that is signed by the Prime Minister.

Nearly all matters concerning nuclear activities in France are regulated through government ordinances (degrets or arretes). The only legal act providing explicit legislative approval for nuclear matters is the Bill on Protection and Control of Nuclear Materials of May 25, 1980. This act does not, however, provide a general legal base for nuclear power plant regulation. Governmental ordinances applicable to nuclear plants can be divided into two categories:

- ordinances concerning safety of nuclear installations in general or safety in handling nuclear material in general
- special ordinances concerning individual installations (e.g., construction or operating licenses of named units).

Construction permits and operating licenses are, as a rule, granted by governmental ordinances. General requirements prerequisite to a construction permit are defined in a decree of December 11, 1963, as amended February 26, 1974, and December 6, 1974. These amending decrees address specifically the issues related to pressurized water reactors.

The license to build and operate a nuclear power plant is granted by the Department for Industry, which also acts as a supervisory authority for operating plants. The licensing proceedings take place in the national capitol. Regionally, a public inquiry is held at the proposed location of a new plant. This inquiry is headed by the regional administrator, and deals only with site-specific aspects, e.g., water consumption or environmental matters.

Due to this centralized organization, responsibilities in nuclear matters are organized vertically. Supervision and licensing of nuclear power plants fall within the jurisdiction of the Department of Industry, which has a special organizational unit, the Central Service for Safety of Nuclear Installations (SCSIN). The SCSIN has two consulting bodies consisting of senior administrators and technical experts that report directly to it:

- The Section Permanente Nucleaire (SPN) has the task of developing the rules and regulations concerning nuclear power plants.
- The Commission Centrale des Appareils a Pression (CCAP) has the task of further developing rules and regulations regarding pressurized systems in general.

Because most regulatory matters deal with nuclear power plant safety and the complete range of handling fissionable materials (fabrication, transport, marine propulsion, refabrication, etc.), an Interdepartmental Committee (CISN) was established in 1975 to coordinate all governmental actions "to protect people and property against dangers of any nature resulting from construction, operation or dismantling of (stationary or mobile) nuclear installations as well as all stages of handling of fissionable materials or radioactive wastes."

Of somewhat lower hierarchical rank, but still of eminent importance, is the Atomic Energy Commission (CEA). Wholly state-owned, the CEA has become not only the expert authority on all nuclear matters, but also the major economic entity controlling a sizeable sector of all parts of the French nuclear market. Rules and regulations developed by the CEA or one of its organizational units are adopted and made official through the decrees, Official interpretations of decrees come from the Department of Industry. The various supervisory boards of the CEA encompass state representatives, public interest groups, e.g., (trade unions), the EdF and major banking houses.

Quality Program Requirements. There is only one governmental ordinance and its official interpretation (circulaire) that explicitly addresses QA/QC matters at nuclear installations: Both exist in draft form as of September 1983. The draft papers are as follows:

- Directive Regarding Quality Design, Construction and Operation of Nuclear Installations
- Circular Regarding the Application of Regulations on Quality of Design, Construction and Operation of Nuclear Installations.

The directive and circular define a general provision for the regulatory authority to intervene in any particular case if there is a suspected shortcoming in safety or quality-related matters.

The directive places responsibility for quality assurance at a nuclear installation on the applicant/licensee for all phases of design, construction and operation. For each system or component, the level of quality to be guaranteed is correlated with its safety importance. The applicant/licensee must install a QA system that takes into account:

- definition of safety requirements and quality standards system-by-system, taking into account all applicable regulations and standards
- design of a QA system
- implementation of a QA system
- installation of a special organizational unit for quality assurance
- documentation of all measures taken
- provision for the required number of adequately trained personnel for QA/QC activities
- provision for adequate technical resources

- updating of the QA system itself in step with advancing technical knowledge

- explicit and definitive procedures to be followed in case of off-normal events

- complete and readily accessible documentation of all steps taken.

Portions of the outlined QA procedure may be performed by suppliers of parts and subsystems on behalf of the applicant/licensee. The applicant/licensee has then the duty to supervise and control the suppliers' QA/QC activities. In any case, the applicant is required to submit to the licensing and supervisory authority (in this case, the Control Service for Safety of Nuclear Installations, SCSIN) a (provisional) safety report on the installation. The QA/QC system of the applicant and the ways and means of supervision of the suppliers' activities are defined in this report.

The chairman of the SCSIN may require additional measures to be taken by the applicant/licensee and may control adherence to these measures. In case of dispute, the applicant may appeal to the Minister of State for Research and Industry.

In addition to the (provisional) safety report, the licensee is required to assemble a QA manual defining all QA/QC measures (technical, organizational and personnel) taken, including surveillance measures over suppliers.

The directive is officially interpreted by an accompanying circular. Of special interest in the circular are the following points:

> The applicant/licensee is in principle responsible for safety of the installation through all stages of design, construction and operation. He may delegate the responsibility for safety and quality of subsystems or parts to suppliers, but ultimate responsibility remains with the applicant/licensee. The licensee must be sure that suppliers who perform QA duties on his behalf strictly adhere to the approved procedures.
>
> The applicant/licensee has some flexibility in defining the range and extent of "safety-related activities" (including their application to activities of subcontractors). The regulatory authorities do, however, reserve judgment on the applicant's views through approval/disapproval when the provisional safety report is submitted.
>
> The applicant/licensee is assigned an important role in supervising the activities of his suppliers. The supplier has to prove to the licensee's satisfaction that he has an adequate QA system. The applicant/licensee may transfer his duty of surveillance of suppliers' activities onto third-party independent experts or expert institutions. Authorized experts/expert institutions are required to be independent of contractual or economic ties with suppliers they are to control.

The supplier of subsystems or parts may define adequate levels of safety and quality for their products; however, the applicant/licensee having ultimate responsibility for the safety of the installation must approve them.

Quality Program Implementation. The licensee is required to submit safety reports that correspond to defined stages of the project:

- A preliminary report that gives an overview of general design criteria aimed at safe operation of the plant

- A provisional safety report that gives detailed design information (including safety and quality standards), demonstrates adherence to applicable norms and regulations, and gives preliminary information towards an operating license

- A final safety report that includes documentation of QA/QC during the construction phase and commissioning test.

Again, the high level of standardization for "series type" PWR nuclear power plants causes a high level of standardization in the safety reports and the licensing proceedings.

During construction, an onsite resident government inspector overviews the QA/QC activities. A major onsite quality control inspection effort is provided by "authorized experts." These inspectors are individuals or staff from small associations under contract to the utility who have been examined and certified by the government's Nuclear Safety Inspectorate. In addition to the certification, the individual inspectors take an oath of office and essentially function as government deputies. The utility also performs onsite quality control inspections.

The Design and Construction Standards for nuclear power plants are planned to be a comprehensive, self-contained set of standards. The AFCEN, an organization encompassing representatives from industry and the EdF, set up the RCC-codes, a consistent system of rules and standards applying to all safety and reliability aspects of nuclear installations. The RCC-Code is published through the Association Francaise de Normalization (AFNOR), which is comparable to the ANSI organization in the United States.

The RCC-Code refers to the nuclear island. Many rules of the RCC-Code are similar to parts of the ASME code, which may be explained by the fact that Framatome developed its standard PWR from a Westinghouse design. One example of the similarity between RCC and ASME codes is that the RCC-M code divides the components of the nuclear island into three classes according to their safety importance. Since the complete RCC-Code is not finalized, existing standards from other technical fields and from the ASME Code are referenced for convenience.

Like the ANSI in the U.S., the AFNOR in France defines general technical standards and codes of practice and keeps them updated. The licensee is free in principle to define the systems according to safety requirements as perceived by him. However, the regulatory authority, in this case primarily the SCSIN, has to concur.

Overall, the French QA/QC system is characterized by three elements:

- Regulatory control measures are predominantly organization-oriented. They consist primarily of auditing and approving QA/QC systems implemented by the applicant or by suppliers.

- With regard to PWRs, the high degree of standardization of plants facilitates regulatory tasks. There are only two basic plant designs (900 and 1300 MWe), one vendor (Framatome), and one applicant/licensee (EdF). This assures maximum nuclear experience in all groups involved.

- The central role of the CEA (and all its organizational affiliates) ensures that maximum experience on all technical or organizational aspects is available.

D.4.6.4 Japan

Japan began using nuclear power plants to generate electricity in 1966. As of March 1984, 25 reactors were in operation (18,277 MWe), 12 (11,804 MWe) were under construction and 7 (6,053 MWe) were in planning. The annual capacity factor has improved in recent years, to 71.5% for 1983. This is a significant load factor considering the obligated three-month downtime for in-service inspection. Nuclear power plants currently produce 20% of the electricity generated in Japan.

The German system of Civil Law was introduced into Japan almost a century ago. Over time, this system was developed and modified to fit Japanese customs. After World War II, this system was exposed to a great amount of information from the U.S. In technical and administrative areas, where governmental influence was not significant, many aspects of the U.S. system were implemented, and today many of the Japanese codes and standards refer to the technical requirements of U.S. codes and standards. Administrative areas in Japan's heavy industries have not been so strongly influenced by the U.S. system.

In the nuclear industry, Japan's QA program was introduced through U.S. companies, such as General Electric and Westinghouse, which contracted with the Japanese utilities to construct nuclear power plants. For the initial construction projects, the regulatory authority performed its duties similar to practice with conventional power plants. QA practices were passed on to subtiered contractors through Japanese vendor-vendee relationships. These QA practices emphasized inspections and records rather than system design and performance.

Organization. The regulation of nuclear power plants in Japan is conducted in accordance with the Electric Utility Industry Law (EUIL) and the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (LRNR). The LRNR was established in 1957. Until 1978, the Japanese Atomic Energy Commission (AEC) had the responsibility for both nuclear development and nuclear safety. The Law for Revision of the Atomic Energy Law enacted in 1978, established the Nuclear Safety Commission (NSC) to control nuclear safety. These laws do not include requirements for quality assurance: however, the Ministry of International Trade and Industry (MITI) has imposed administrative guidelines requiring a QA program.

MITI has the authority to issue licenses for the construction and operation of commercial nuclear power plants in Japan. The Prime Minister and Minister of Transportation has the authority to issue licenses for the construction and operation of research reactors and nuclear vessels respectively. Under the EUIL, applicants for a license to construct a commercial nuclear power plant (research and ship reactors are covered by different organizations) must submit siting data for environmental impact review by the MITI. The MITI reviews the data with consultation from the Committee on Environmental Matters, and then holds public hearings where local governments and citizens participate. Once site approval has been obtained from the local governments, the MITI submits the application to the Electric Power Resources Development Coordination Council for its approval. Before issuing a license for construction, the MITI also consults with the AEC and the NSC about the reactor design.

The Japanes nuclear power program has a large number of participants compared to many other countries. Nine private utilities have nuclear power plants in Japan.

The Ministry of International Trade and Industry (MITI) also includes the Agency of Natural Resources and Energy (ANRE) and advisory committees on both environmental matters and nuclear power technology. MITI is responsible for commercial nuclear plant licensing and safety regulations on all the construction, maintenance and operation stage. The MITI provides technical reviews for the licensing of commercial reactors and conducts safety reviews of their installation. The MITI inspects operating reactors. The MITI currently has about 50 people on its staff who perform technical safety and licensing reviews of commercial nuclear power plants in support of the STA's administrative responsibility for licensing review. The MITI has approximately 100 people qualified to perform inspections.

The Science and Technology Agency (STA) is an administrative body attached to the Prime Minister's office. The STA has both management and technical review responsibility for research reactors and reactor systems still under development.

The Atomic Energy Commission (AEC), which is responsible for nuclear development, is made up of five Commissioners appointed by the Prime Minister with the consent of both houses of the Diet. The AEC is an advisory body to the Prime Minister concerning the development and use of nuclear power.

The Nuclear Safety Commission is also made up of five Commissioners and is under the authority of the Prime Minister. This commission is an advisory body to the Prime Minister concerning the safe use and regulatory requirements of nuclear energy.

The Japanese Institute for Nuclear Safety (JINS) was recently formed within the Nuclear Power Engineering Test Center (NUPEC) as a joint venture of the MITI and the STA. The JINS assists the MITI and the STA in the technical regulation, licensing, and standards development for nuclear power plants.

Quality Program Requirements. The laws governing construction and operation of commercial nuclear power plants in Japan do not specifically include quality assurance. Administrative guidelines imposed by the MITI on licensees do, however, include some requirements for QA, but these guidelines are not as specific as those in 10 CFR 50 Appendix B. Instead, the licensee's QA program is expected to include those QA/QC elements that have evolved during the development of Japan's nuclear power program. Certain inspections are required by the EUIL and LRNR laws, including inspection of components and structures during manufacture, installation and construction, and inspection of welds.

In 1972, the first QA standard for construction of nuclear power plants was published by the Japan Electric Association. The Nuclear Safety Standards (NUSS) program established by the International Atomic Energy Agency (IAEA) in 1974 was another impact on both governmental agencies and utilities. The Japan Electric Association revised the QA standard (JEAG-4101) according to IAEA QA Code of Practice in 1981, and has been preparing additional QA guidances corresponding to IAEA safety guides. For domestic nuclear contracts, JEAG-4101-1981 is referred to in procurement documents and is used as the criterion to survey, audit and quality the vendors.

ASME Stamp Association, starting from 1973, had a strong impact on Japanese heavy industries, especially for nuclear installations. ASME survey teams have taught QA concepts and importance of QA program maintenance. Now, in Japan, many factories hold ASME Stamps and most of the sub-tiered contractors have QA manuals similar to the ASME QA manual.

In concert with the NUSS program of the IAEA, two programs have emerged. The first program established a QA Investigation Committee under MITI, which is the responsible regulatory and enforcement agency for construction and operation of nuclear power plants. Established in 1980, this committee 1) analyzes nonconformities reported from utilities, 2) identifies QA problems with suppliers, and 3) investigates QA practices in the U.S. and Europe. The committee recommended the introduction of QA programs recognized in the U.S. and in European countries with some modifications suitable to Japanese industries.

The second program established the Committee for Nuclear Accreditation organized under the Japan Power Plant Inspection Institute (JPPII), which is authorized to inspect the nuclear power plant components on behalf of MITI. MITI has the procedures and criteria to qualify the manufacturers of nuclear power plant components concerning welding, but it is most concerned with the capability of facilities and personnel, not with the details of the QA programs. The committee has discussed the introduction of a system similar to the ASME "N" Stamp Accreditation system, and is also considering establishing a third-party agency to conduct surveys and audits.

Quality Program Implementation. The initial phase of the inspection program takes place to following issuance of the license and prior to authorizing construction. This plan includes details of the design (technical specifications), methods of construction, and a general description of the QA program. As part of the construction plan approval, the licensee must convince the MITI that the QA program meets the MITI administrative guidelines for quality assurance. QA program review at this stage is normally limited to the general description with a limited review of procedures. While it may appear that, in the absence of QA criteria, it would be difficult to meet the guidelines, the system apparently works well due to a limited number of licensees, most of them having prior nuclear experience.

The licensee has primary responsibility for QA inspections, and the MITI performs inspections on an oversight basis as necessary to meet their legal responsibilities. MITI inspections are normally a review of documentation, with limited hardware inspection except for those specifically required by law, e.g., reactor vessel, reactor cooling system, containment, etc. In addition to the inspection of specific documentation, the MITI also performs audits of the licensee's QA program to verify compliance with commitments made in the construction plan. If problems are discovered during the audit, the MITI may choose to perform a more detailed inspection of documentation and hardware.

While the MITI has approximately 100 inspectors, the level of effort expended on direct inspection activities is limited. Inspection activities at construction sites consume about 200 man-days for each nuclear power unit being constructed. The inspections are scheduled when required, depending on construction activities being performed. At present, the MITI is trying to relieve inspectors at each of the nuclear power plants. The MITI staff is relatively fixed due to budgetary restraints, and the number of reactors is increasing. Future inspections will be less technical and more programmatic than current inspections, resulting in an inspection program that will be primarily an auditing activity.

The Electric Utility Industry Law requires inspection of welds in vessels that contain radioactive fluids or that fulfill a safety-related function. The MITI is responsible for inspection of such welds. The actual inspection is performed by the JPPII, a non-profit organization established in 1970. The JPPII performs inspection of welds and administers tests for welding procedure qualification and welder qualification. It is funded by the users of its inspection services, who pay a fee for each inspection. The MITI has licensed the JPPII to perform weld inspections and almost all other hardware-type inspections of operating plants that the MITI is required by law to perform periodically. When the JPPII performs an inspection, no additional inspection is peformed by the MITI.

The JPPII has nore than 100 inspectors who perform required inspections for new as well as for operating nuclear plants. No estimate was available form the MITI as to the total JPPII effort expended per year for each nuclear power unit under construction.

To further the effectiveness of the audit program, in the past year the MI has instituted team inspections. These are audits by a team of three to fou inspectors, conducted during a period of three to four days. The team inspections are performed annually and, among other inspection activities, review the QA program in more detial than was done previously. It was reported that the team inspections (audits) have not uncovered any major problems.

The relationship between the MITI and licensees (and their contractors) is one of mutual trust and cooperation. All parties share a common goal, to build nuclear power plants that can be operated safely. The MITI stresses that their role is to oversee the licensee; the licensee is responsible for controlling activities of contractors.

Licensee requires submittal of detailed construction design approval including QA program. Requirements for inspections, other than MITI-required inspections, are the responsibility of the licensee. Therefore, the licensee establishes the inspections to be performed by the licensee and by contractors. Likewise, qualificaiton of licensee/contractor inspection personnel is the responsibility of the licensee. When the MITI requires specialized knowledge for an inspection, they normally expect the licensee/contractor inspectors to satisfy themselves that the technical requirements have been met.

D.4.6.5 Sweden

The Swedish nuclear power program began producing electricity in 1972, and by the end of 1982 had 10 operating reactors with a capacity of 7330 MWe. The average annual load factor in 1982 was 68.3%, and nuclear power produced 39% of the electricity in Sweden. Sweden currently has two power reactors under construction which will add 2110 MWe to the capacity. Three of the reactors were supplied by Westinghouse, and ASEA/ATOM developed the remainder. ASEA/ATOM, which is owned equally by ASEA and the Swedish government, designs and supplies BWR systems and fuel. ASEA/ATOM has had a technical exchange program with the General Electric Co. which has resulted in an American influence on Sweden's QA programs. ASEA/ATOM also functions as the architect-engineer and construction manager-contractor for the mechanical systems. By popular vote in 1980, a moratorium on nuclear power was approved which precludes the construction of additional units beyond the two currently being built. When these two are completed, nuclear power will provide nearly 50% of Sweden's total electrical energy (NEI 1983) .Organization. Nuclear installations in Sweden are governed primarily by the Atomic Energy Act of 1956. Other acts regulating nuclear power in Sweden are the Radiation Protection Act of 1958, the Emergency Preparedness Act of 1960, the Atomic Liability Act of 1968, and the act regulating special permission to load nuclear reactors (1977) (Stevenson and Thomas 1982). Another act relating to construction and considered applicable to nuclear power plants is the Building Act of 1947.

Licenses for nuclear power reactors are issued by the Swedish government according to the Atomic Energy Act of 1956. This Act places the responsibility for licensing with the Ministry of Industry. The Swedish Nuclear Power Inspectorate (SKI) administers the licensing process and reports to the Ministry of Industry. The granting of a license for a nuclear power plant by the Ministry of Industry is subject to approval by the Parliament. The SKI uses 10 CFR 50 Appendix B from the United States as a guideline for the scope of the QA program. The SKI has issued control procedures relevant to quality assurance of nuclear power plant construction.

There are six major participants in the Swedish nuclear power plant construction program:

- Ministry of Housing
- Swedish Nuclear Power Inspectorate (SKI)
- National Institute of Radiation Inspection (SSI)
- Swedish Plant Inspectors (SA)
- Utilities (SSPB, FKG, Sydkraft, and OKG)
- ASEA/ATOM.

If the proposed plant is to be constructed on a new site, the Building Act states that permission is required from the concerned municipalities before construction can began. The Building Act empowers local administrations to regulate construction in the vicinity of nuclear power plants, and also applies to establishing other types of industrial operations. The Licensing Board for Environmental Protection issues conditions and directives.

Two government agencies in Sweden are involved in the licensing and inspection of nuclear power plants. The SKI, under the Ministry of Industry, is responsible for technical and safety aspects of the nuclear power program. The other agency, the SSI, under the Ministry of Agriculture, reviews license applications and inspects facilities with respect to radiation protection and environmental impact of radioactive releases. Both agencies are relatively small. The SKI currently has about 80 employees, and 17 of the total 150-person staff of the SSI are assigned to nuclear powers matters. Funding for both agencies is provided by fees paid by the applicants or licensees. A third agency, the Labour Protection Board (KAS), provides assurance of the pressure circuits. The KAS regulates the design, manufacture, and construction of all industrial plants which present potential hazards other than radiation.

The SKI is the component of the Ministry of Industry that is responsible for administrating the licensing process for nuclear power plants. The SKI consists of five members appointed by the government, who are assisted by a staff and advisory committees. The advisory committees consist of chairmen and at least four members nominated by the government from the SKI and its staff.

The SKI's primary objective is to promote safety in nuclear power plants. It reviews safety assessments, inspects nuclear installations, and initiates research and development (R&D) within the field of nuclear safety. The SSI is the national authority for radiation protection for both occupational and environmental exposures. Its scope includes external and internal environments, and emergency planning. The SSI works with local authorities in preparing emergency plans.

The Swedish Plant Inspectorate (SA) is a nonprofit, government-owned company, formed in 1975, which performs third-party inspection and testing. It has a staff of 540 which is organized into pressure vessel engineering, machinery engineering, nuclear plant inspection, and four regional offices that perform inspections of shops, lifting devices, and pressure vessels. The SA is funded by fees for specific inspection and testing activities. Until 1975, there were two important nonprofit companies in Sweden which specialized in quality verification. These companies had shareholders, some of whom were involved in nuclear projects, and the government established SA based on the existing organization of these two companies to ensure independence of the project inspection agency.

Quality Program Requirements. The Swedish licensing procedure is basically a four-step system (Stevenson and Thomas 1982):

- The plant owner prepares a PSAR and applies for a construction permit. The SKI and the SSI grant permits for construction.
- The plant owner transmits data to the SKI demonstrating capability to meet conditions in approval license, and components and systems are tested as the plant is constructed.
- The plant owner submits a FSAR, and after SKI approval a fuel loading and reduced power permit is issued.
- The SSI reviews radiation protection and informs the SKI of its approval, who if satisfied, issues the operational license.

The owner is required to establish a QA program which meets the formal commitments for QA in the PSAR and is approved by the SKI. The SKI has utilized the criteria in 10 CFR 50 Appendix B as guidelines for quality assurance. The RKS has developed guidelines specific to the Swedish conditions, and, although not approved by the SKI, the utilities have been using these guidelines as a basis for internal QA work.

General inspection plans for safety class items were originally established by the utilities and approved by the SKI. These plans then developed into standardized inspection plans issued by the SKI. The general inspection plan identifies the documentation, inspections, tests, and examinations which are required for the various activities, and lists the responsibility for performing each. The SA has specified responsibilities to perform, review, verify, and report on certain of the tests, inspections and examinations. The SA inspects (including nondestructive testing) the pressure containment features in the power plants in addition to such inspection by the utility. The licensee may use independent inspection agencies, which includes SA, for its inspection activities.

Plant designs, inspection plans, and fabrication/work plans and procedures are all reviewed by the SA and approved before the licensee or vendor can proceed with specific activities. In essence, a "hold point" system is used and enforced by the SA. The SA supervisor designated for each nuclear power plant must be approved by the SKI. This supervisor must report to the SKI that the plant is satisfactorily completed before fuel loading and start-up operations can begin.

Quality Program Implementation. Four utilities operate or build nuclear power plants in Sweden. One is state owned, one is privately owned, and two are consortiums of local governments. These consortiums were established specifically to build and operate nuclear power plants. As owners, they have the overall responsibility for the design, construction, startup, and operation of nuclear power plants. The four owners have formed the Nuclear Safety Board of the Swedish Utilities (RKS), a joint body for collaboration in safety matters. The RKS collects, processes, and evaluates information on operational disturbances and incidents at Swedish and foreign nuclear power plants, and devises common policy and standards. Requirements for quality assurance were established in 1982 and then received trial use. In 1983, the RKS sent the QA requirements to the SKI and requested that they be designated as the reference for quality assurance of nuclear power plants in place of 10 CFR 50 Appendix B.

The largest utility is the state-owned Swedish State Power Board (SSPB), which provides approximately 45% of Sweden's capacity. The SSPB has five operating reactors plus one under construction. The Thermal Design Department has overall responsibility for quality assurance. It assigns QA functions to other components of the SSPB, and reviews and approves both internal and contractor procedures. The QC group is responsible for the quality of all mechanical equipment and assists in the preparation of specifications, reviews contractor proposals, prepares inspection plans and performs contractor surveillance for both manufacturer and site installations. The SSPB has a group to collect and analyze operations information with the objective of improving quality and reliability; arrangements have been made with the other Swedish utilities and some foreign utilities to exchange operating data and reports on failures, repairs, modifications and maintenance.

Sweden has used two systems for building nuclear power plants. The first two plants were obtained on a turnkey basis. For the remaining plants, the utilities used another system whereby the plants were divided into several large packages with the utility as overall coordinator: nuclear island, turbine-generators, and structure. The construction contract is normally a cost-plus system combined with economic incentives.

The nuclear steam supply system for nine of the twelve plants was provided by the same company, ASEA/ATOM. ASEA-ATOM's business is primarily the Swedish nuclear power plants, but it has also supplied two reactors to Finland and is supplying components to other countries in Western Europe. ASEA/ATOM's manager of design and development has overall responsibility for quality assurance and is directly responsible for design control. The production manager is responsible for compliance with the QA program. The program is set up with one individual responsible for each type of component or equipment. Design criteria are described in the design basis documentation which is included in a proposal and negotiated as part of a contract. The contractual design basis documentation is subject to formal change controls and customer approval. Quality verification is contracted to an independent inspection agency which prepares detailed procedures. While performing quality verification, the inspection agency compiles inspection reports on behalf of ASEA/ATOM.

For the remaining three plants, the steam supply system was supplied by Westinghouse. This arrangement has facilitated the use of replicated designs, with usually three or four units being built from the same basic design. ASEA/ATOM's first unit was supplied on a turnkey basis, and for the others, ASAE/ATOM functioned as the A-E for the mechanical systems that they supplied and as the construction manager/contractor for the mechanical systems that they subcontracted.

Most Swedish nuclear power plants have been built in a relatively short time (four to six years), and most of the activity is performed by experienced personnel who are with a job through completion. While there is a somewhat adverse relationship between the regulators/inspectors (SKI, SSI, SA) and the builders (the utilities and ASEA/ATOM), the limited resources of a small country (eight million people) and stability of the industry result in the interaction being less formal than in other countries.

The fabricator-installer provides "special" inspection plans, based on the general inspection plan, which cover the specific items being fabricated or installed. Special inspection plans are submitted to ASEA/ATOM for approval and for forwarding to the SA for approval. Following SA approval, the vendor can proceed with the specific activity covered by the plan.

Official third-party inspections are required by statute for certain activities and components and are performed by the SA. Further inspection and testing not required by statute may be prescribed by the owner, and the owner normally designates an independent agency to perform these inspections and tests. The SA designates a supervisor for each nuclear plant. This supervisor, who must be approved by the SKI, is responsible for ensuring that the plant meets codes, standards and requirements. The SKI has one inspector per unit. This inspector is not a resident but keeps frequent contact with construction, utility and other SKI personnel.

The program for nuclear power plant construction in Sweden has taken advantage of replicated designs and stability of personnel involved in the construction. The government regulatory agencies in Sweden have relatively small staffs and rely on independent-third party reviews and inspections. The utilities and the nuclear steam supply system supplier have taken an active role in formulating QA policy and in working with the regulators to adapt requirements to the Swedish environment.

D.4.6.6 The United Kingdom

In 1956, the United Kingdom (UK) initiated commercial nuclear generation of electricity when it began operating four 50-MWe reactors at Calder Hall. Until 1968, the UK had the largest nuclear power capacity in the world with 17 reactors producing electricity. Currently, the UK has 32 reactors producing 16% of the country's electricity. Forty-two reactors are projected for 1990 with a capacity of 12,514 MWe.

Unlike the United States, the UK regulatory agency does not prescribe the detailed methods for the compliance and implementation of the QA/QC requirements as part of the statutory regulation. The regulatory agency promulgates only the more general requirements in the form of guidelines for the safety and quality assurance for licensing. The licensee (utility is responsible for developing detailed requirements and for implementing safety and QA procedures that will satisfy the broad requirements of the regulatory agency.

Although the UK nuclear industry has had over two decades of QA/QC programs for nuclear plant design and construction, the Heysham II AGR plant (1978) is the first nuclear power plant in the UK with a license specification (1978) containing a formal QA requirement. The UK's QA/QC program is in a state of transition from gas-cooled reactor technology to PWR technology, and the British are taking steps to incorporate U.S. QA/QC requirements into their system. Therefore, the emerging UK QA/QC program will be a blend of U.S. requirements and British industry practices.

Organization. The main legislative acts governing commercial nuclear power plants in the UK are the Nuclear Installations Acts of 1965 and 1969 and the associated provisions of the Health and Safety at Work etc. Act of 1974. The Nuclear Installations Acts provide the regulatory framework for licensing of commercial nuclear power plants by the Health and Safety Executive (HSE). Under these Acts, no site may be used for the purpose of installing or operating a commercial nuclear installation unless a nuclear site license has been granted by the HSE. These Acts lay down only general requirements for the safety of nuclear power plants, and impose an absolute liability upon the licensee for any injury or damage caused by the release of radioactive material from its installations. The licensee is also responsible under the Health and Safety at Work Act for the safe design and operation of nuclear installations to ensure the health and safety of employees and other persons.

There are a limited number of major participants in the UK nuclear power program, and the character of those organizations has been changing in recent years. A description of their roles, internal organization and interrelationships is presented here. The four major participants in the UK nuclear power program are the HM Nuclear Installations Inspectorate (HMNII), the Central Electricity Generating Board (CEGB), the National Nuclear Corporation (NNC), and the major contractors (national and private). The Nuclear Installations Inspectorate (NII) was established in 1960 and became a part of the HSE when that organization was set up in 1975. The HSE brought together a number of existing inspectorates, including the Nuclear Installations Inspectorate, the Factor Inspectorate, the Alkali and Clean Air Inspectorate, and the Mines and

Quarries Inspectorate.

The HSE is a corporate body able to take independent action on safety enforcement, although it takes its general policy instructions from the Health and Safety Commission (HSC). The HSC then reports to the Secretary of State for Employment.

On nuclear safety matters, the HSC reports directly to the Secretary of State for Energy and to the Secretary of State for Scotland. While these Ministers have a limited power of directing, the NII operates independently of any government department.

The NII is organized under the Chief Inspector into four branches, each headed by a Deputy Chief Inspector. Three branches are responsible for the work on commercial nuclear power stations. Of these, one branch deals with future systems, and at present gives priority to the Inspectorate's assessment of the pressurized water reactor (PWR program). The fourth branch is responsible for the licensing of installations concerned with fuel fabrication and reprocessing, isotope separation and waste management. Inspectors in each section carry out such detailed work such as design safety assessments, quality assurance assessments, site inspections and other work connected with licensing. There are approximately 100 staff members, more or less evenly allocated among the four branches.

In addition to the NII, there is a further independent body, the Advisory Committee for the Safety of Nuclear Installations (ACSNI), which advises the HSC and the appropriate secretaries of State on major issues affecting the safety of nuclear installations that are referred to it or that it considers in need of attention. The ACSNI's function is to provide advice on policy matters rather than become involved in the regulatory process.

The CEGB is the government-owned utility that is responsible for design, construction and operation of nuclear power plants in England and Wales of the UK. An equivalent role is played by the South of Scotland Electricity Board (SSEB) for the regions of Scotland, but the scope and capacity of the SSEB is much smaller than the CEGB. Since the governing laws and regulatory requirements for nuclear power generation are the same for both England and Scotland, the SSEB practices are similar to these of the CEGB in licensing nuclear power plants. Consequently, this discussion is limited to the CEGB and its roles in the overall nuclear program of the UK.

The CEGB, as the owner and operator of commercial nuclear power plants, is responsible for the safety of its employees and the public from any nuclear hazard arising from its installations. This responsibility is formally defined in the Nuclear Installations Acts of 1965 and 1969. These Acts impose an absolute liability upon the CEGB, as licensee, for any injury or damage caused by the release of radioactive material from its installations. Recognizing this responsibility, the CEGB is committed to maintaining the highest nuclear safety standards to ensure the radiological protection of the employees and the public. The safety standards established by the CEGB are generally acceptable to the NII and are reviewed regularly in light of scientific and technical developments.

Among the departments and divisions of the CEGB, the following organizations have direct bearing on the safety of nuclear power plants:

- Health and Safety Department (HSD). The HSD is the primary interface for the CEGB with the NII. It is independent of all other parts of the CEGB organization, and its director reports directly to the Chairman and Executive of the CEGB. The HSD is responsible for assessing and monitoring the CEGB's activities to ensure a satisfactory standard of nuclear safety and compliance with regulatory requirements during all phases of the project and the subsequent operational lifetime and decommissioning. The HSD is also responsible for consultation and liaison with the NII on all licensing matters, including quality assurance, to obtain formal approvals under the nuclear site license.

- Generation Development and Construction Division (GDCD). The GDCD's major responsibility is designing and constructing nuclear power stations. Within the CEGB, the GDCD has total responsibility and authority for the design, procurement, manufacture and construction during the construction phase of a nuclear power station, responsibility including verification that QA/QC programs are satisfactorily implemented in the constituent phases. The GDCD is also responsible for developing and implementing relevant QA/QC program procedures from design through to commissioning and for establishing appropriate interface procedures for all principal participants.

- Technology Planning and Research Division (TPRD). The TPRD operates three CEGB laboratories involved in research work associated with nuclear technology, nuclear safety, fuel performance, materials science, thermal hydraulics, radiological protection and water chemistry.

- Nuclear Operations Support Group (NOSG). The NOSG administrates the CEGB's procedures to satisfy the conditions of the nuclear site licenses and coordinates the preparation of safety submissions to the Nuclear Safety Committee.

- Transmission and Technical Services Department (TTSD). The Engineering Services Department of TTSD is responsible for developing the CEGB's corporate policy on QA practices and for providing certain QA services to the GDCD.

- Nuclear Power Training Center (NPTC). The NPTC is used to train nuclear plant operators. Training is conducted primarily with simulators.

- Regions. The immediate delegated responsibility for operating a nuclear power station and for ensuring that QA practices are followed during plant operation rests with the Station Manager. This person is accountable through the CEGB's Regional line management to the Regional Director-General.

Quality Program Requirements. Although the NII does not issue standards or codes of practice for nuclear power plants, it does formulate and enforce the general requirements for the safety and the quality of the plant design, construction and operation. The NII's general requirements are set forth in a document entitled A Guide to the Quality Assurance Program for Nuclear Power Plants.

The NII is responsible for ensuring that the licensee develops and maintains appropriate standards that meet the general requirements of the NII and for monitoring and enforcing the quality of design, construction, and safe operation of the plant. This responsibility includes inspecting for compliance with the requirements at all stages of plant construction, operation, and decommissioning.

The applicant is granted a nuclear site license following a satisfactory outcome of the NII's review and assessment of the documents and preliminary plant design submitted by the applicant. Granting of a site license signifies that the NII is satisfied that the design intent, safety principles, and contract design description are such that construction can proceed with little risk of significant changes being subsequently required for safety reasons.

The NII maintains close surveillance, during construction, of the licensee's activities to ensure that the licensee follows appropriate QA/QC practices in construction. The NII's site inspector visits the site (average every two to four weeks) for inspection purposes, witnessing tests and examining test records. Where necessary, NII inspectors visit manufacturers' shops to monitor fabrication, witness tests and audit QA/QC procedures.

Some of the specific requirements and procedures that are followed during the construction phase to ensure quality of construction are listed below:

- The licensee must make arrangements for inspection and testing of major items of the plant both on-site and at manufacturer's shops. These activities may be carried out either by recognized independent inspecting agencies or by the licensees' own inspection organization, but the arrangement requires approval of the NII.

- The licensee must keep detailed case histories of the construction of important items such as pressure vessels, which must be retained throughout the life of the plant.

- The licensee must formulate appropriate QA/QC procedures that must be approved by the NII.

- The licensee must update the PCSR by a Station Safety Report (equivalent to U.S. FSAR) as the design and construction approach completion, which forms the basis of the NII's acceptance of the station for commercial operation.

- The licensee must obtain the NII's consent to proceed further at various major steps in the construction phase.

The QA/QC practices of the UK nuclear industry are based on two primary documents. These are BS-5882, Total Quality Assurance Programme for Nuclear Power Plants (1980); and NII/R/38/78/Issue 2, Guide to the Quality Assurance Programme for Nuclear Power Plants (1980).

BS-5882 closely parallels Appendix B to 10 CFR 50 and ANSI N45.2, and establishes the QA principles for the UK nuclear industry. The implementation methods of the principles are set out in another standard called BS-5750, Quality Systems, that consists of six parts delineating specific procedures for implementing the BS-5882 principles. NII/R/38/78 is the Guidelines document issued by the NII and is the Assessment Criteria Document for NII inspectors.

Quality Program Implementation. In implementing the QA program requirements of BS-5882 for design, procurement and construction of nuclear power plants, a graded categorization system is applied to various items. The QA category of an item or service is assigned according to its safety importance or operational reliability and performance importance. Factors considered in assigning the level of QA requirements for an item are as follows:

- the consequence of malfunction or failure of an item
- the design and fabrication complexity or novel features of an item
- the need for special controls and surveillance over processes and equipment
- the degree to which functional compliance of an item can be demonstrated by inspection or test
- the quality history and degree of standardization of an item
- the difficulty of repairing or replacing an item, or its accessibility for in-service inspection.

Essentially there are two QA category levels assigned to various plant items and services at a typical nuclear power station. The "Q" category is assigned to items and services of safety class, and the "N" category is assigned to non-safety class items and services. However, in practice the UK uses four grades of QA requirements to categorize control and verification requirements at nuclear power stations. The various grades of QA requirements for plant items and services are as follows:

- "Q". Items and services categorized as "Q" are subjected to the highest grade of control and verification requirements. These include all safety class plant items and services of a nuclear power plant.

- "N/S," "N/O." "N/S" includes items and services "Important to Safety." "N/O" includes items and services "Important to Operational Reliability."

- "N/E." The "N/E" grade is assigned to those items and services that are non-safety, non-operationally significant, but require significant design engineering by the contractor or manufacturer.

- "N/-." This grade is assigned to non-safety, non-operationally significant, off-the-shelf items that are mass-produced by a routine production process.

The "Q" graded items and services are required to satisfy BS-5882 QA program requirements. Items designated as "N" grade are not required to satisfy the BS-5882 requirement but must meet standards of quality assurance appropriate to the contract specifications.

An important aspect of the UK QA/QC practices is the so-called "hierarchical system," in which the extent of responsibility and authority and the line of communication channels are clearly defined in a descending order starting from the licensee at the top, through the main contractor and finally to the smallest supplier at the bottom. Although a higher-order organization may audit the QA/QC practices of any lower-order organization, an organization is only accountable to the organization immediately above it in the hierarchy. Under this hierarchical system, the CEGB interfaces with the National Nuclear Corporation (NNC) on all matters concerning quality assurance within the UK PWR program. The NNC was incorporated in 1974 as a partially government-funded (35%) private nuclear engineering company, and is the only such company in the UK. The NNC is a contractor to the CEGB, and is responsible for its own QA/QC practices as well as for those of other suppliers. A Joint Project Team (JPT) is formed, primarily of NNC and CEGB staff, and is responsible for developing, coordinating, and monitoring the implementation of the project QA program at all project stages. Contractors are responsible to the JPT for the quality of the products and services they supply to the CEGB. Each purchaser, including the NNC acting as the CEGB's agent, is responsible in turn for ensuring that each supplier has acceptable QA/QC programs and procedures and for verifying that the performance of each supplier against these procedures is appropriate.

An Independent Third Party Inspection Authority (ITPIA) is employed by the GDCD to provide independent services involving all items procured to the intent of Section III of the ASME Boiler and Pressure Vessel Code. The ITPIA undertakes the tasks ascribed to an "Authorized Inspection Agency" in Section III of the ASME Code as adapted by the CEGB and NNC for use in the UK.

The underlying characteristic of regulatory practices in the UK is that the regulatory agency emphasis is on the actual accomplishment of the licensee in the safe design, quality construction, and safe operation of nuclear power plants rather than on documentation requirements.

Another point of interest about regulatory practices in the UK is that the responsibility for safety is placed on the licensee (utility), requiring it to formulate the design safety criteria and standards, QA standards and implementing procedures. The UK approach to safety does not accept the premise that designers and operators ensure safety by meeting a prescribed standard or guidance set by the regulatory agency.

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APPENDIX E

GLOSSARY OF ACRONYMS/ABBREVIATIONS

GLOSSARY OF ACRONYMS/ABBREVIATIONS

ACRS	Advisory Committee on Reactor Safeguards
A/E	architect-engineer
A&E	architectural and engineering
AEC	Atomic Energy Commission
ANSI	American National Standards Institute
ASLB	Atomic Safety and Licensing Board
ASME	American Society of Mechanical Engineers
ASQC	American Society for Quality Control
AWS	American Welding Society
CAT	Construction Appraisal Team
CM	construction manager
CP	construction permit
CPE	Construction Project Evaluation
CRGR	Committee to Review Generic Requirements
DOE	Department of Energy
DR	designated representative
FAA	Federal Aviation Administration
FSAR	Final Safety Analysis Report
HARC	Human Affairs Research Center
IDCVP	Independent Design and Construction Verification Program
IDI	integrated design inspection
IDVP	Independent Design Verification Program
IE	Office of Inspection and Enforcement
IEEE	Institute of Electrical and Electronics Engineers
INPO	Institute of Nuclear Power Operations
MarAd	Maritime Administration

NASA	National Aeronautics and Space Administration
NB	The National Board of Boiler and Pressure Vessel Inspectors
NRC	Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NSSS	nuclear steam supply system manufacturer
OTA	Office of Technology Assessment
PAT	Performance Appraisal Team
PNL	Pacific Northwest Laboratory
PSAR	Preliminary Safety Analysis Report
PUC	Public Utility Commission
QA	quality assurance
QC	quality control
SALP	Systematic Assessment of Licensee Performance
SRP	Standard Review Plan
TPT	Torrey Pines Technology
USN	U.S. Navy

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16. ABSTRACT *(200 words or less)*

At the request of Congress, NRC conducted a study of existing and alternative programs for improving quality and the assurance of quality in the design and construction of commercial nuclear power plants. A primary focus of the study was to determine the underlying causes of major quality-related problems in the construction of some nuclear power plants and the untimely detection and correction of these problems. The study concluded that the root cause for major quality-related problems was the failure or inability of some utility managements to effectively implement a management system that ensured adequate control over all aspects of the project. These management shortcomings arose in part from inexperience on the part of some project teams in the construction of nuclear power plants. As a corrollary, NRC's past licensing and inspection practices did not adequately screen construction permit applicants for overall capability to manage or provide effective management oversight over the construction project. The study recommends a number of improvements in industry and NRC programs.

17. KEY WORDS AND DOCUMENT ANALYSIS	17a. DESCRIPTORS
Quality	Management Capability
Quality Assurance	Prior Experience
Quality Control	Architect-Engineer
Design	Construction Manager
Construction	Constructor
Commercial Nuclear Power Plants	Utility
Ford Amendment	

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