1.0 INTRODUCTION

1.1 PURPOSE OF THE REPORT

In recent years, major problems relating to the quality of design and/or construction have arisen at several nuclear power plant construction projects. Projects having received widespread attention in this regard include Marble Hill, Midland, Zimmer, South Texas, and Diablo Canyon. Because of these quality-related problems and others in the U.S. nuclear industry, many in the public and in Congress have questioned (1) the nuclear industry's ability to design, construct and operate reactors in a manner consistent with maintaining public health and safety, and (2) the Nuclear Regulatory Commission's (NRC's) ability to provide effective regulatory oversight of these activities. As a result of these Congressional concerns, the NRC was directed by Congress in Section 13(b)* of Public Law 97-415 (the NRC Authorization Act for fiscal years 1982 and 1983) to conduct a study of existing and alternative programs for improving quality assurance and quality control in the construction of nuclear power plants. The study requirements of that law are as follows:

Sec. 13(b) The Commission shall conduct a study of existing and alternative programs for improving quality assurance and quality control in the construction of commercial nuclear powerplants. In conducting the study, the Commission shall obtain the comments of the public, licensees of nuclear powerplants, the Advisory Committee on Reactor Safeguards, and organizations comprised of professionals having expertise in appropriate fields. The study shall include an analysis of the following:**

(1) providing a basis for quality assurance and quality control, inspection, and enforcement actions through the adoption of an approach which is more prescriptive than that currently in practice for defining principal architectural and engineering criteria for the construction of commercial nuclear powerplants;

(2) conditioning the issuance of construction permits for commercial nuclear powerplants on a demonstration by the licensee that the licensee is capable of independently managing the effective performance of all quality assurance and quality control responsibilities for the powerplant;

- *This amendment to the NRC Authorization Act was introduced by Senator Wendell, Ford of Kentucky and was co-sponsored by Senators Simpson, Mitchell, Levin, and Hart. It was called the "Ford Amendment" by its sponsors and this term is adopted in this report.
- **These five alternatives will frequently be referred to as "alternatives b(1)-b(5)" in the remainder of this report.

(3) evaluations, inspections, or audits of commercial nuclear powerplant construction by organizations comprised of professionals having expertise in appropriate fields which evaluations, inspections, or audits are more effective than those under current practice;

(4) improvement of the Commission's organization, methods, and programs for quality assurance development, review, and inspection; and

(5) conditioning the issuance of construction permits for commercial nuclear powerplants on the permittee entering into contracts or other arrangements with an independent inspector to audit the quality assurance program to verify quality assurance performance.

For purposes of paragraph (5), the term "independent inspector" means a person or other entity having no responsibility for the design or construction of the plant involved. The study shall also include an analysis of quality assurance and quality control programs at representative sites at which such programs are operating satisfactorily and an assessment of the reasons therefor.

(c) For purposes of ---

(1) determining the best means of assuring that commercial nuclear power plants are constructed in accordance with the applicable safety requirements in effect pursuant to the Atomic Energy Act of 1954; and

(2) assessing the feasibility and benefits of the various means listed in subsection (b);

the Commission shall undertake a pilot program to review and evaluate programs that include one or more of the alternative concepts identified in subsection (b) for the purposes of assessing the feasibility and benefits of their implementation. The pilot program shall include programs that use independent inspectors for auditing quality assurance responsibilities of the licensee for the construction of commercial nuclear powerplants, as described in paragraph (5) of subsection (b). The pilot program shall include at least three sites at which commercial nuclear powerplants are under construction. The Commission shall select at least one site at which quality assurance and quality control programs have operated satisfactorily, and at least two sites with remedial programs underway at which major construction, quality assurance, or quality control deficiencies (or any combination thereof) have been identified in the past. The Commission may require any changes in existing quality assurance and quality control organizations and relationships that may be necessary at the selected sites to implement the pilot program.

(d) Not later than fifteen months after the date of the enactment of this Act, the Commission shall complete the study required under subsection (b) and submit to the United States Senate and House of Representatives a report setting forth the results of the study. The report shall include a brief summary of the information received from the public and from other persons referred to in subsection (b) and a statement of the Commission's response to the significant comments received. The report shall also set forth an analysis of the results of the pilot program required under subsection (c). The report shall be accompanied by the recommendations of the Commission, including any legislative recommendations, and a description of any administrative actions that the Commission has undertaken or intends to undertake, for improving quality assurance and quality control programs that are applicable during the construction of nuclear powerplants.

This report describes the activities and results of the special study of quality assurance required by the Ford Amendment. Congress' action to elevate concern for quality in construction of commercial nuclear power plants to the national level will be of continuing help to the NRC in attaining its goals for quality in the nuclear industry.

In its 1984 "Policy and Planning Guidance" to the NRC staff, the Commission states its policy for raising the quality of nuclear plants as follows:

Policy:

- 1. The NRC must improve its activities that affect quality in the nuclear industry. NRC's goal is to assure a high level of quality in management of reactor design, construction, operations, and maintenance.
- 2. For both construction activities and operating facilities the NRC needs to understand the causal factors leading to problems and to develop a modified institutional and legislative framework for future nuclear plants which will decrease the probability of repetition of past mistakes. The theme of "do it right the first time" should be adopted to ensure plants are built properly and can operate safely.
- 3. In order to reduce operational problems including maintenance and modification activities, the NRC needs to pursue more aggressively efforts (1) to assure utilities provide the appropriate management framework and capability for safe operation and maintenance of nuclear power plants; (2) to improve quality in utility operations and in procedures, systems, and components used in operations; and (3) to develop better guidance for the treatment of plant systems, components, and equipment that can adversely affect safe operation.
- 4. NRC should highlight the necessity for highly trained and qualified professionals for licensees, contractors and vendors to manage those functions that relate to safety.

This study reflects the above Commission policy statement. It is a look to the future--an opportunity for a mid-course correction that builds upon past experience to chart a future course for assuring quality in nuclear power plant design and construction. While this study has looked at the past, it has been from the perspective of what should be done in the future.

In any complex endeavor, some errors will be made. The more complex the endeavor, the greater the chance of errors. If some risk is associated with the endeavor, measures must be taken to provide assurance that errors are found, corrected, and do not pose an undue threat to public health and safety. Construction of nuclear power plants is a very complex endeavor, and uncorrected errors in construction may seriously threaten public health and safety when operation begins. The primary measure used by the nuclear industry to provide assurance that construction errors are found and corrected is a quality assurance (QA) program. As used by the NRC, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service. Quality assurance includes "quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component or system which provide a means to control the quality of the material, structure, component or system to predetermined requirements."*

Congress has posed several very specific questions, and this study undertakes to answer those questions. However, to provide a foundation for the answers to those specific questions, the study sought also to answer the following underlying questions:

- 1. Why have certain nuclear construction projects experienced significant quality-related problems while others have not?
- 2. Why have the NRC and the utilities failed or been slow to detect and/or respond to these quality-related problems?

The answers to these underlying questions provide a foundation for answering the following question which, in the NRC's opinion, summarizes the thrust of the Ford Amendment:

3. What changes should be made to the current policies, practices, and procedures governing commercial nuclear power plant design, construction and regulation to prevent major quality problems in the future or to provide more timely detection and correction of problems?

These questions helped to focus the study activities and approach, and their answers provided the central themes for this report to Congress.

Perhaps equally important to stating what questions this study did answer is to state what questions it did not answer. Primary among questions that this study did not answer are the following:

*Code of Federal Regulations, Title 10, Part 50 (10 CFR 50), Appendix B.

- (1) This study did not attempt to quantify the relationship between quality and quality assurance and safety, nor did the study develop a quantifiable relationship between risk and quality assurance. In particular, this study did not address the question of the extent to which the quality or quality assurance problems that occurred at plants such as Marble Hill, Midland, Zimmer, South Texas, or Diablo Canyon may have affected the safety of those plants.
- (2) This study did not address the issue of quality and quality assurance for operating plants.
- (3) This study did not develop a methodology to measure the effectiveness of quality assurance programs. In particular, this study did not attempt to evaluate the effectiveness of various non-NRC QA programs covered in the study, including those of other government agencies, other industries, or other countries, but rather sought to identify individual features of those programs that should be considered for adoption in NRC's program.
- (4) The study took as a given that NRC's statutory role is not to ensure the survival of the nuclear option but rather to ensure that if nuclear power is used in the U.S., such use is consistent with maintaining the common defense and security and public health and safety. Consistent with this premise, the study (1) did not consider the appropriate role of nuclear power in the U.S.'s national energy policy, (2) did not attempt to determine whether NRC's present statutory role should be changed, and (3) did not attempt to assess the future of nuclear power in the U.S. or the effect of quality assurance programs on that future. Exploration of such questions is beyond the statutory purview of the NRC. In this regard, the Congressional Office of Technology Assessment (OTA) has recently published a major study that deals with these issues: Nuclear Power in an Age of Uncertainty.* The OTA report and this study complement each other in many ways and, while dealing with overlapping issues from different perspectives, each reinforces findings of the other (e.g., the critical role of utility management in constructing and operating nuclear power plants, and predictability in the licensing process).

Each of these questions was considered outside the scope of this study, which was tailored to be as responsive as possible to the specific questions asked by the Ford Amendment.

This report focused on developing an understanding of the quality or quality assurance problems that have occurred in plants currently under construction. Some of these projects have experienced problems in plant quality--parts of the plants were built incorrectly. Some of these projects experienced problems in

^{*}U.S. Congress, Office of Technology Assessment. February 1984. OTA-E-216, Washington, D.C.

the assurance of quality--the utility was unable to demonstrate whether its pant was built correctly. Some projects experienced problems in both quality and the assurance of quality. To acknowledge this overlap, the report throughout will refer to problems in quality and/or quality assurance or quality and the assurance of quality, etc. For simplicity of writing, problems generally falling under this umbrella will sometimes be referred to as "quality-related" problems.

1.2 ROLES OF THE NRC AND UTILITIES IN NUCLEAR CONSTRUCTION

Before describing the study activities and results, the statutory role of the NRC in nuclear construction, quality and quality assurance should be made clear. The NRC is not directly responsible for nuclear power plant quality. The public policy of the United States, established in the Atomic Energy Act of 1954, is that ownership and operation of commercial nuclear power plants rest in the hands of the public and privately owned utilities of the United States, but only to the extent their use is consistent with the common defense and security and the public's health and safety. The Act directs the NRC to issue licenses only to persons "who are equipped to observe and who agree to observe such safety standards to protect health and to minimize danger to life or property as the Commission may by rule establish."*

It is the owner/licensee who is responsible for achieving and assuring the quality and reliability of a nuclear power plant. The designers, the constructors, labor contractors, and component vendors are responsible to the licensee to the extent that the owner/licensee delegated responsibility. However, ultimate responsibility, even though delegated, is retained by the licensee.** The NRC is responsible for the health and safety of the public, not the quality or lack of quality of the nuclear power plant. If the licensee has not fulfilled its responsibility for building a safe plant, the NRC can still fulfill its responsibility by denying an operating license.

However, neither the interests of the public (who may also happen to be the owners, stockholders and/or customers of the utilities) nor the utilities are well served by a regulatory system that introduces uncertainty about the ultimate acceptability of an expensive and long-in-the-making facility until its completion date. All parties are best served by a regulatory process that establishes relevant standards, exercises due process in the change of those standards, screens out at the beginning those organizations that are not equipped to attain those standards, provides inspections that effectively measure the attainment of those standards in a time frame that permits corrective action as early as possible and takes enforcement action in all cases where corrective action is not adequate, and finally provides reasonable confidence that a project has demonstrably met all requirements and can be operated safely. Many of this study's recommendations, when implemented, should improve NRC's ability to provide such a regulatory process.

*Atomic Energy Act of 1954, as amended, Section 103(b)(2).

**10 CFR 50, Appendix B.

1.3 EVOLUTION OF NRC PROGRAMS FOR QUALITY ASSURANCE

It is important to understand the evolution of the regulatory framework within which the major quality-related problems have occurred. The regulatory framework governing the nuclear industry has developed and changed along with the nuclear industry over the years, often in response to specific events. The major quality-related problems at the five nuclear projects cited previously provide a new set of events and programmatic failures that will lead to further evolution of the regulatory framework. The purpose of this study is to provide direction for that evolution and also to identify any factors that may be beyond NRC's regulatory purview but that may have contributed to those major quality-related problems.

The following sections describe the evolution of quality assurance requirements and guidance, quality assurance licensing programs, and quality assurance inspection programs.

1.3.1 Quality Assurance Requirements and Guidance

In July 1967, the Atomic Energy Commission (AEC) published for public and industry comment Appendix A to 10 CFR Part 50, "General Design Criteria for Nuclear Power Plants." Among the 55 criteria in Appendix A covering plant design, one criterion required a quality assurance program for certain structures, systems and components. Following review, public comments, and subsequent revisions, Appendix A was issued as an effective regulation in February 1971. Although its criterion for the QA program was very general, the July 1967 draft of Appendix A was the first AEC proposal that would require nuclear power plant licensees to have a quality assurance program.

The lack of AEC requirements and criteria for quality assurance was a key issue raised by the Atomic Safety and Licensing Board (ASLB) in the operating license hearings for the Zion plant in 1968. The board ruled that until the licensee presented a program to assure quality and until the AEC developed criteria by which to evaluate such a QA program, the hearings would be halted. Following the board's rulings, the AEC developed requirements and criteria for quality assurance programs and prepared a proposed new regulation, Appendix B to 10 CFR Part 50, which would require licensees to develop programs to assure the quality of nuclear power plant design, construction, and operation.

Appendix B contains 18 criteria that must be a part of the quality assurance program for safety-related systems and components. Experience from military, the National Aeronautics and Space Administration (NASA), and commercial nuclear projects, as well as the AEC's own nuclear reactor experience, was used in developing the criteria. Appendix B clearly places the burden of responsibility for quality assurance on the licensee. Although the licensee may delegate to others the work of establishing and executing part or all of the quality assurance program, the licensee retains responsibility for the program. Visible QA documentation is required for all activities affecting the quality of safety-related systems. Appendix B was published for comment in April 1969 and implemented in June 1970.

In addition to establishing QA regulations (i.e., Appendices A and B) in the early 1970s, the AEC and the industry began issuing guidance that provided acceptable ways of meeting the intent and requirements of the specific regulations. In October 1971, the American National Standards Institute (ANSI)

issued N45.2, "Quality Assurance Program Requirements for Nuclear Power Plants." This standard was subsequently endorsed by the AEC in Safety Guide 28 (now Regulatory Guide 1.28) in June 1972. In 1973-1974, the AEC issued three guidance documents for quality assurance in design and procurement, construction, and operation to help licensees establish QA programs. In July 1973, two AEC Commissioners and senior AEC staff participated in a series of regional conferences with utilities to explain the role of quality assurance in designing, constructing, and operating nuclear power plants and the NRC's role in licensing, inspecting, and implementing licensee's quality assurance programs. Since 1970, as the nuclear industry grew, as experience was gained in nuclear regulation, and as the need for such guidance was recognized, many consensus standards and AEC/NRC regulatory guides have been developed and published to address various aspects of quality and quality programs.

1.3.2 Quality Assurance Licensing Programs

Appendices A and B of 10 CFR 50 set quality assurance requirements but left open the issue of how to meet them. Industry standards were subsequently developed, and AEC guidance documents for quality assurance were prepared and published. The standards and guidance documents helped both the AEC and the license applicants understand what quality assurance is and how the quality assurance program should function. AEC staff guidance was prepared for the licensing staff to use as criteria for evaluating licensees' applications.

In the early 1970s, the regulatory staff believed that license applications should contain additional information on the licensee's quality assurance programs. In an effort to establish standards for the licensees' description of their QA program in their construction permit applications, a proposed "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants" was issued for comment in February 1972 and later adopted. After the new standard was developed, a staff Standard Review Plan (SRP) was published in 1974 and adopted in 1975 to standardize and guide the licensing staff in its review of license applications. Licensing staff use the SRP as a benchmark in reviewing the QA programs of license applicants. Updated and revised versions of the SRP have been issued about every three years since.

1.3.3 Quality Assurance Inspection Programs

Before 1968, the AEC performed little inspection at nuclear power plants under construction. Few inspection procedures and only minimal guidance were available. As a result of quality-related problems in the construction of some nuclear power plants, including the Oyster Creek plant in New Jersey at which major problems in vendor-supplied materials were discovered, the AEC recognized the need to examine construction activities more closely and to develop more formalized programs for inspecting construction activities. The AEC reassigned inspectors from operations to construction and hired personnel with construction backgrounds.

As the number of inspectors and reactors increased, so did the need for more inspection guidance. The AEC began developing a "General Facility Under Construction Inspection Program" and began writing inspection procedures to implement the program. In late 1969, the AEC issued a directive to the regional compliance offices to implement the procedures. In 1972, a procedure entitled "QA During Design and Construction" was issued. This procedure addressed Appendix B of 10 CFR 50 and required a review of the licensee's quality assurance manual, a meeting with corporate utility management, and an initial inspection after the construction permit application was docketed but before it was issued.

In 1973, more detailed inspection procedures were issued covering pre-docketing and pre-construction permit inspections. The AEC then began preparing a more comprehensive inspection program, which greatly expanded and clarified the inspection program during the pre-construction and post-construction permit issuance period. These inspection programs have basically the same structure today as when the major revised programs were issued in 1975. However, major changes have recently been made to refine and prioritize the inspection procedures, to increase inspection coverage with resident inspectors and team inspections, and to direct more inspection effort to independently confirming the quality of hardware and completed work and less inspection to quality assurance documentation and programmatic aspects.

1.4 PROJECT TECHNICAL APPROACH

The findings, conclusions, and recommendations of this study are based on the following project activities: (1) case studies of several commercial nuclear power plant projects that have had major quality-related problems in design and construction and several that have not; (2) pilot programs to assess the feasibility and benefits of third-party inspections to evaluate QA program effectiveness; (3) evaluation of audits of nuclear power plant construction by the Institute of Nuclear Power Operations (INPO); (4) analysis of the feasibility and benefits of a more prescriptive approach for defining principal architectural and engineering criteria; (5) review and analysis of NRC's organization, methods, and programs for quality assurance; (6) analysis of project, organizational, and institutional issues associated with quality in nuclear power plant design and construction; (7) review of other selected programs for the assurance of quality, including programs of other U.S. government agencies, other industries, and foreign countries; (8) consultations and interaction with the public, licensees, the Advisory Committee on Reactor Safeguards (ACRS), associations of professionals and others to solicit their ideas and input; and (9) establishment of a group of outside senior and expert consultants to provide individual comments on study activities and findings.

Because the case studies and pilot program involved some common sites (Marble Hill, South Texas, and Palo Verde), they may be confused with each other. In the case studies, six projects were analyzed to identify the reasons for the success or lack of success of their quality assurance programs, whereas the pilot program was a test of the use of independent auditors at four sites to evaluate QA program effectiveness. Although the pilot program audits did analyze the quality assurance programs of four different licensees and over-lapped some case study activity, the desired result from the pilot program was an assessment of whether independent, third-party audits could feasibly enhance the detection capability currently provided by existing NRC and licensee programs.

1.5 PUBLIC COMMENTS

Because only fifteen months were available to complete the required analyses and to prepare this report, time was not available to publish preliminary study findings for public comment. The NRC elected to request public comments on the Ford Amendment at the beginning of the study so that the comments could be used to develop and refine the study plan. The NRC did not want to develop a study plan and discover, through a later public comment process, that a significant item had been missed and could not be added because of time. Some of the comments received were used in conducting the study, and several of the study conclusions support comments received. As a result, many of the comments that were received have been adopted within NRC's planned actions or included in issues slated for further study. The resulting study plan was presented at a public meeting of an ACRS subcommittee in July 1983.

To provide some outside review, the NRC arranged for nine persons who were independent of the NRC to examine NRC's plans and progress several times during the study. These outside professionals had expertise in nuclear power plant quality assurance, project management, engineering, and other relevant areas. The names, positions, and a summary of the comments of the reviewers are contained in Chapter 10 of this report.

1.6 ORGANIZATION OF THE REPORT

Based on the previously described project activities, the remainder of this report is organized as follows. Chapter 2 is a summary of the report and contains the study findings, conclusions, actions and recommendations. Chapter 3 describes findings from the case studies and contains an assessment of the reasons the quality programs at some nuclear projects have operated satisfactorily while others have not. The case study methodology, analysis and findings are described in more detail in Appendix A. In Chapter 4, the pilot program and the results of the pilot program analysis are described. This chapter also includes an analysis of the feasibility and benefits of conditioning construction permits on a positive post-construction permit demonstration of the applicant's QA management ability and on the applicant's entering into arrangements with third parties to audit its QA program performance. Chapter 5 is an analysis of the benefits and feasibility of audits by associations of professionals, with a focus on the INPO's Construction Project Evaluation program.

Chapter 6 is an analysis of the benefits and feasibility of adopting a more prescriptive approach to defining principal architectural and engineering criteria. Chapter 7 contains the results of an analysis of the NRC's organization, methods and programs for quality assurance. Appendix B, which is an analysis of the NRC's QA program by a management consulting firm, covers the NRC program in more detail. Chapter 8 contains the results of an analysis of contractual, organizational, and institutional issues associated with quality in nuclear power plant design and construction. The issues in this section emerged as a result of other study activities, and the results of this analysis help provide a more comprehensive understanding of indirect factors that have some effect on quality in the nuclear industry. A more detailed analysis of these issues is found in Appendix C.

Chapter 9 contains the results of a review of selected quality programs outside the U.S. commercial nuclear industry, including those of other government agencies, other industries and foreign countries. The purpose of this outside program review was to identify aspects of other programs that could be translated to the NRC program and might improve the NRC program. Appendix D contains a more detailed analysis of this review. Neither the Chapter 8 nor the Chapter 9 analyses were required by the Ford Amendment, but they were included in the study to provide a broader spectrum of information and analysis from which to draw findings and conclusions and to develop recommendations. Chapter 10 briefly summarizes information received from the public, licensees, the ACRS, associations of professionals, and the special review group established for this study, together with NRC's response to the significant public comments received.

The report has been structured so that Chapters 3 through 10 individually describe the analyses and study results summarized in Chapter 2. Each of Chapters 3 through 10 has been written as a stand-alone document so that anyone who is interested in a particular subject (e.g., more prescriptive architectural and engineering criteria) can read the chapter pertaining to that subject and understand the study's conclusions on that subject without having to read the rest of the report. The study's major results, conclusions and recommendations are summarized in Chapter 2. This organization has resulted in some necessary redundancy between Chapter 2 and the rest of the report to achieve the goals of (1) summarizing the study results in one place, and (2) covering each major topic in a self-contained, stand-alone treatise.

· · ·