POLICY ISSUE
(Information)

[illegible]

[illegible]: The Commission

[illegible]: William J. Dircks
Executive Director for Operations

Subject: INFORMATION REPORT ON [illegible] LICENSEE QUALITY ASSURANCE PROGRAMS AND [illegible] DESIGNATED REPRESENTATIVES

Reference: Memorandum to W. J. Dircks, EDO from S. J. Chilk, SECY, dated October 7, 1982 on Staff Requirements - Briefing on Quality Assurance (SECY Reference M820929)

Purpose: To provide the Commission with an information report on the status of the staff's conceptual review of (a) a program requiring certification of quality assurance compliance at certain hold points during nuclear power plant construction, and (b) a program using designated representatives to carry out activities on behalf of the NRC.

Background: SECY-82-352, "Assurance of Quality" (August [illegible], 1982), [illegible] initiatives designed by the staff to improve confidence in the quality of construction of nuclear power plants. One of these initiatives is the concept of an NRC designated representative (DR) program, analogous to the Federal Aviation Administration (FAA) system of designated representatives. At the September 29, 1982 Commission briefing on the quality assurance (QA) initiatives (SECY-82-352), the Commission [illegible] to explore further the concept of using [illegible] representatives in the NRC inspection program.

During the briefing, Commissioner [illegible] to pursue the idea of [illegible] [illegible] current requirements for [illegible] mentation of a licensee's QA program [illegible] construction.

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In discussing these new QA programs and concepts, it is important to have a common understanding of what is meant by quality assurance and the responsibilities of the NRC and NRC licensees. Quality assurance, as defined in Appendix B to 10 CFR 50, comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Based on existing legislation and current NRC practice, NRC licensees have the responsibility for the design, construction, and operation of the nuclear power plant in accordance with applicable standards and regulations. The NRC has the responsibility to ensure that the licensee fulfills its responsibilities to design and construct a nuclear power plant that can be operated in a manner consistent with public safety. The decision whether a permit or license may be issued and/or continued rests with the NRC.

Discussion: This paper provides a status report on the staff's efforts to study the concepts of an NRC certification program and the role of the designated representative. The main body of this paper briefly summarizes the staff's actions and plans; the enclosures provide a more detailed discussion of the issues and concerns encountered in exploring these new and alternative program ideas.

The third Commission request, to identify the current NRC hold points, was addressed by the Office of Policy Evaluation (OPE) in a memorandum to the Commission dated November 15, 1982. OPE identified four hold points which are currently employed by the NRC: (1) issuance of a limited work authorization (LWA), (2) issuance of a construction permit (CP), (3) issuance of a low-power operating license (OL), and (4) issuance of authorization for full-power operation. The staff agrees that OPE correctly characterized the existing hold points.

Certification Program

A certification program would require, in effect, written confirmation by the NRC, licensee, or both, of the capabilities, readiness and implementation of quality assurance programs at certain points during the construction of a nuclear power plant as a prerequisite to proceeding with construction. Most NRC programs are presently oriented to provide verification of licensee performance and to identify unresolved or open items and items of noncompliance. Assurance is obtained by the appli-

of significant issues in the area reviewed. The certification program concept under review would require an assessment of the existing and prospective capabilities and readiness of the licensee to proceed. The concept of evaluating the capability and readiness of a licensee to proceed or continue activities represents a significant expansion in current NRC practice.

The staff has considered two types of NRC certification programs. One approach would require a "formal" NRC review and certification at certain major milestones in a plant's construction. All licensee activities would stop at each milestone. No construction activities could be continued or initiated until NRC certification to proceed is obtained. This approach has two major drawbacks: (1) it would prolong the construction period between the issuance of the CP and OL and (2) the required NRC certification appears to be a "license" under the Administrative Procedure Act which might require the NRC to seek an amendment to the Atomic Energy Act. The second approach would require reviews and certifications by both the licensee and the NRC. This approach would consist of a system or hierarchy of control points which provide for statements by the licensee of readiness to initiate new activities at major milestones in a plant's construction, for periodic reviews and certifications by the NRC of licensee performance and readiness to proceed, and for certifications by the licensee, NRC, or both, of completed activities. This approach does not have any built-in delays in the construction process and does not appear to require any amendments to the Atomic Energy Act. The staff is in the process of further studying this certification program concept. A brief description of the three types of control points being considered is provided below:

a. Evaluation of preparations for beginning a new activity. This control point would be an evaluation at major milestones in a plant's construction. Before the initiation of new activities, the licensee would be required to demonstrate that, based on past performance and on the capabilities and readiness of the licensee's staff and programs, it is ready to initiate the new activity. Ongoing activities would normally not be affected by this control point. NRC review and acceptance of the licensee's report would be required. This control point is referred to as a "hold point."

b. Evaluation of performance over a set period of time. This control point would establish an integrated evaluation (both retrospective and prospective evaluations) and would be conducted periodically (for example, annually like SALP). NRC action may be taken if the review identified deficiencies. This control point is referred to as a "review point."

c. Evaluation and acceptance of a completed activity, structure, system, or component. This control point, of which there would be many, would be a continual and ongoing evaluation process. This effort would be basically an extension of inspection and observation of work activities, coupled with a certification of acceptance of the completed activity. This control point is referred to as an "acceptance point."

Detail on the basis, rationale, and implementation of each of these points is identified in Enclosure 1 to this paper. The implementation of this system of control points (hold points, review points, and acceptance points) between the issuance of the CP and OL would reduce the time intervals between NRC evaluation of the adequacy and quality of plant construction and of the licensee's capability to proceed. The shorter time intervals for review should increase the likelihood of early detection of problems affecting the quality of the construction, as well as provide a stronger base from which the NRC can ensure that the plants are adequately built.

The staff is currently expanding these concepts of hold, review, and acceptance points into a more definitive program. The impact on resources, both NRC and licensee, must be evaluated. Possible milestones and frequencies for each of the control points must be identified and coordinated with other NRC Offices, especially ELD, NRR and the Regional Offices. The program concept and ideas will be discussed with industry.

In development of this issue, staff will examine the policy, practicality, and legal problems as well as the time frame required for implementation of these control points, identifying those concepts that can be implemented in the short term and those that may require an extended period of time (for example, rule change). The staff plans to carry out the above activities over the next few months and report back to the Commission by July 31, 1983.

Designated Representative

The concept of the designated representative (DR), analogous to that employed by the Federal Aviation Administration (FAA), is a quality assurance initiative that the staff has been reviewing for a number of months. The designated representative as evaluated in this paper would be an individual employed by a licensee, architect/engineer (A/E), applicant, or other firm who would be assigned by the NRC to perform certain specified activities on behalf of the NRC. The designated representative would represent an extension of the NRC inspection program and would carry out activities that are clearly delineated and that would be evaluated against specific criteria.

As described in more detail in Enclosure 2, there are significant differences between the FAA and NRC. Both agencies regulate a private industry, but the FAA regulates an industry that replicates many similar finished products. The DR evaluates and certifies, for the FAA, completed activities at certain points in the production process. The NRC regulation of nuclear power plant construction, while having many intermediate milestones, involves the production of one unique product by each utility. The NRC certification of this product may be considered to be the OL, compared to the FAA certification of the airworthiness of each airplane produced. To make the FAA/NRC analogy more exact, the NRC would have to expand its certification activities to include, for example, the concept of acceptance points (discussed above) which basically would then create a role for the DR in the NRC program. In this capacity, the DR would act for the NRC in evaluating and certifying completed activities. The DR would represent an extension of resources available to the NRC to carry out inspection activities.

An additional point to consider is the long lead time required to implement a DR program. The staff estimates that at least three years would be required to make the necessary changes to the Atomic Energy Act and the NRC regulations, develop a DR certification program, and select and certify the designated representatives. Given the current balance of nuclear plants under construction and anticipated completion dates, this program implementation may not be a near-term practical remedy to prevent deficiencies in the quality of construction such as experienced recently in some facilities.

Future Plans

The staff plans to complete its analysis of the concept of developing a certification program employing designated hold points, review points, and acceptance points; coordinate the program with other NRC Offices; obtain industry comments; and report back to the Commission by July 31, 1983. The study of the role of the designated representative in the NRC program is closely linked with the development of the acceptance point concept in the certification program.

Some of the ideas and concepts identified in the studies can possibly be implemented more in the near term than the three-year lead time noted for the DR program. Hold points could be implemented by adding or revising conditions of a construction permit or amending the regulations. Review points could be implemented by revising existing NRC programs and reviews (for example, SALP). The staff's assessment of the time period required to implement these concepts will be included in the July 1983 report.

The studies of a certification program and a designated representative program are initially focused on the construction phase of a nuclear power plant. The staff recognizes that these concepts may also have applicability to the operations phase of nuclear power plants and the staff plans to pursue this issue upon completion of its review of the construction phase. Note that the quality assurance issues discussed in this paper are closely related to the issues identified in the 1982/1983 NRC Authorization Act (Ford Amendment). It is the staff's intention to coordinate this review with the quality assurance studies required by Congress.

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Enclosures:
1. Certification Program
2. Designated Representative Program

Enclosure 1

CERTIFICATION PROGRAM

Background

During the September 29, 1982 briefing on SECY-82-352, "Assurance of Quality," Commissioner Gilinsky requested that the staff pursue the idea of a program requiring NRC certification of licensee quality assurance (QA) programs as a prerequisite for going beyond certain hold points. He also requested at this briefing that the staff determine NRC's current requirements for certifying the implementation of a licensee's QA program during certain stages of construction. Earlier in July 1982, Commissioner Gilinsky requested the Office of Policy and Evaluation (OPE) to identify the steps in power reactor construction and initial testing where NRC control points could usefully be established.

In response to Commissioner Gilinsky's request, OPE prepared a report entitled, "Regulatory Review and Associated Hold Points During Nuclear Power Plant Construction and Testing," dated November 15, 1982, which the staff has used in examining the concept of establishing a system for certification of a licensee's implementation of the QA program. There are four formal NRC hold points currently associated with the construction and operation of a nuclear power plant which evaluate the licensee's programs, capabilities and commitments related to nuclear safety. These hold points are: (1) the issuance of a limited work authorization (LWA), (2) the issuance of a construction permit (CP), (3) the issuance of an operating license (OL) for fuel loading and low-power testing, and (4) the authorization for full-power operation. A prospective assessment of a licensee's capabilities and readiness to proceed with construction activities is characteristic of NRC evaluations for issuing of the LWA and CP. A retrospective assessment of the licensee's performance during construction and testing forms, in part, the basis for issuing of the OL. In this paper the term "licensee" is used in an all inclusive sense to include applicants for an LWA, CP holders, and holders of an OL.

Between the CP and OL issuances, the NRC routinely conducts two types of evaluations - the Systematic Assessment of Licensee Performance (SALP) and the "94300" evaluation (named after the IE inspection procedure). These evaluations provide input to the licensing decision-making process. The SALP is an annual evaluation conducted by the Regional Offices for nuclear power plant sites, under construction or operating. The SALP program retrospectively evaluates the licensee's overall performance up to the time of the evaluation. A retrospective focus is also characteristic of the 94300 evaluation. The

94300 evaluation results are transmitted in a memorandum from the Regional Administrator to the Director of NRR following preoperational testing of a new plant and prior to NRC authorization to load fuel and conduct low-power tests. The memorandum compiles and summarizes the results of the routine inspection program and provides a status on the implementation of the licensee's QA program. This memorandum identifies each open item, with status of resolution and significance, status of the inspection program, status of the licensee's testing and systems acceptance programs, and the conditions to be imposed on the licensee. The memorandum is updated monthly until fuel loading. In examining the certification program, the staff considered that the 94300 memorandum represents, in effect, a "certification" by the Regional Administrator of the status of a licensee's QA program implementation and performance. A third evaluation, the Near-Term Operating License (NTOL) evaluation, has recently been implemented as an interim measure to assist the licensing review effort in compiling and evaluating licensee performance in preparation for issuance of the low-power operating license. The NTOL evaluation is conducted only once and that occurs toward the end of construction and preoperational testing.

There is a long interval between the issuance of the CP and the low-power OL, in some cases as long as 10-12 years. Although many inspections of particular technical areas and SALP evaluations occur during this time period and result in summary reports of specific findings, before 1982 there were no documented "integrated" evaluations performed. Integrated evaluations include a retrospective assessment of the licensee's performance to date and a prospective assessment of the licensee's capability and readiness to proceed to subsequent stages of construction and testing. Recently, the staff initiated Construction Appraisal Team (CAT) and Integrated Design Assessment Team evaluations which include both a retrospective and prospective assessment of licensee programs. However, these evaluations are just beginning, still being tested, and with the limited NRC resources available to carry out these reviews, have limited applicability to the total number of sites presently under construction. It should be emphasized that it is only at the time of the evaluations associated with OL issuance that the current NRC programs approximate the performance of an integrated evaluation.

The choice of appropriate control points or milestones is an important element in considering if and when additional integrated evaluations are appropriate. Additional evaluations might be considered when, (1) construction has progressed sufficiently to provide meaningful assessments of elements critical to construction quality, but when construction is still at a point where necessary corrective action may reasonably be undertaken, and (2) when a significant transition occurs in the mix of activities, skills, and requirements associated with further construction and testing.

During the review of the current NRC practices with regard to hold/control points, of certification of a licensee's implementation of QA programs and of CPE's analysis, the staff recognized several problems which are discussed below.

Current Practices - Problem Areas

The current NRC licensing system includes four formal regulatory hold points (LWA, CP issuance, low-power OL, and full-power authorization) which provide for formal NRC certification of licensee programs (including QA programs). The complexity and extent of problems that have been identified in the past few years at units now under construction have raised questions about the quality of the design and construction of certain nuclear projects and the effectiveness of NRC's reviews and inspection and enforcement programs.

A recent analysis of the experience at problem sites resulted in the identification of 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 owner's 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 in order to take appropriate enforcement action.

The first two problem areas have been attributed to a lack of total owner management commitment to quality at the inception of nuclear projects together with a lack of understanding of the role of quality assurance in project management and what is required by personnel at all levels of the project. The QA initiatives proposed in SECY-82-352 are geared toward alleviating these problems.

The third problem has been attributed to shortcomings of NRC's programs in not sufficiently examining project management controls at sites under construction and not addressing design quality as specifically and extensively as other areas. While NRC performs numerous inspections toward establishing adequacy within major technical and functional areas (e.g., concrete, electrical, welding), and several evaluations during nuclear power plant design, construction, and testing, there are no documented evaluations oriented toward prospectively assessing that the licensee has the capabilities to continue with activities.

It can be argued that the NRC framework of regulatory control points, considered together with evaluations and the inspection program, is adequately designed to provide for assessments at a sufficient number of strategic locations that support the primary NRC mission of ensuring that nuclear power plants are

designed, constructed, and operated in a manner consistent with the health and safety of the public. Furthermore, NRC has sufficient statutory authority to take appropriate action at any time that licensee QA performance and capability are assessed as inadequate. It can also be argued that the framework described has not been sufficient to prevent quality assurance problems from occurring and persisting over long periods of time before effective corrective actions are taken.

The actions initiated by SECY-82-352 have addressed the perceived problems; however, there is no specific action to assess prospectively the capabilities of a licensee to proceed with specific activities. The concept of a certification program is being evaluated as a means to provide prospective assessments of a licensee's capability and readiness to proceed with specific activities. The concepts and ideas for a certification program are addressed in the section below.

Certification Program

Most NRC programs are oriented to provide verification of licensee performance and to identify unresolved or open items and items of noncompliance. The concept which Commissioner Gilinsky asked the staff to explore and the programmatic ideas and concepts addressed in the discussion below represent a significant change in current NRC practice. The idea of prospective evaluations concentrates on NRC assessment of a licensee's capabilities and requires either an explicit (formal or written) or implicit (lack of objection) acceptance by the NRC.

The staff has explored various methods of combining a certification program with present NRC practices to increase confidence in the quality of construction of nuclear power plants. One approach would require a "formal" NRC review and certification at certain major milestones in a plant's construction. All licensee activities would stop at each milestone. No construction activities could be continued or initiated until NRC certification to proceed is obtained. This approach has two major drawbacks: (1) it would prolong the construction period between the issuance of the CP and OL and (2) the required NRC certification appears to be a "license" under the Administrative Procedure Act which might require the NRC to seek an amendment to the Atomic Energy Act. The second approach would require reviews and certifications by both the licensee and the NRC. This approach would consist of a system or hierarchy of control points which provide for statements by the licensee of readiness to initiate new activities at major milestones in a plant's construction, for periodic reviews and certifications by the NRC of licensee performance and readiness to proceed, and for certifications by the licensee, NRC, or both of completed activities. This approach does not appear to require any amendments to the Atomic

Act, and its resources and delays impacts appear to be less burdensome than the formal certification process . The development of this control point system is only at an early stage; the concept will be pursued with NRR, ELD and the Regional Offices in evaluating its practicality, usefulness, and legal ramifications.

The staff is presently studying a certification program to provide for the following:

a. Evaluation of preparations for beginning a new activity. This control point would establish an evaluation at major milestones in a plant's construction. Before the initiation of new activities, the licensee would be required to demonstrate that, based on past performance and on the capabilities and readiness of the licensee's staff and programs, it is ready to initiate the new activity. NRC review and acceptance of the licensee's report would be required. This control point is referred to as a "hold point."

b. Evaluation of performance over a set period of time. This control point would establish an integrated evaluation (both retrospective and prospective evaluations) and would be conducted periodically (for example, annually). NRC action may be taken if the evaluation identified deficiencies. This control point is referred to as a "review point."

c. Evaluation and acceptance of a completed activity, structure, system, or component. This control point, of which there would be many, would provide a continual and ongoing evaluation process. This effort would be basically an extension of inspection and observation of work activities, coupled with a certification of acceptance of the completed activity. This control point is referred to as an "acceptance point."

The three sections that follow provide a detailed discussion on each of the three control points identified above.

Hold Points

Current NRC regulations provide for four hold points during which an evaluation is made of a licensee's programs, capabilities and commitments related to nuclear safety and QA compliance. The issuance of a permit or license by the NRC can be considered as a form of certification. Certification by the licensee on the other hand has only recently been requested in connection with the NRC program, whereby the licensee certifies that the facility has been constructed

in accordance with FSAR commitments. As was discussed earlier, the existing CP and OL hold points are too far apart in time to provide timely assurance of continuous quality construction of the nuclear power plant.

Introducing additional hold points of the CP or OL type raises several practical difficulties with regard to both statutory requirements and implementation. The economic impact of a hold point and the costs to the licensee and the NRC must be considered in determining if and when hold points may be appropriate. The hold points should be selected so that the new hold points do not cause any unwarranted delays in the plant construction. The concept of the certification program is being studied and considered as a result of the long time period between CP and OL issuance.

Also, as OPE points out in its report, it may be difficult to justify imposing hold points in every case, in advance of evidence of specific plant inadequacies, or imposing additional holds on further plant construction and testing to await the outcome of the reviews. However, the primary concern in identifying possible new hold points would be, of course, to increase the confidence in the quality of the nuclear power plant being constructed.

The concept of hold points would apply to both prospective and retrospective evaluation - an assessment of demonstrated performance as well as an assessment of the capabilities and readiness of the licensee to proceed. The hold points between the issuance of the CP and OL, presently being considered, would be established at certain major milestones in a plant's construction. At or before each hold point, the licensee would be required to demonstrate that, based on past performance and the capabilities and readiness of the licensee's staff and programs, it is ready to proceed to the next hold point. The present concept for implementing of the hold points is that ongoing construction activities would continue at the hold point, but that the new construction activities planned for initiation at that construction milestone would not be initiated until the NRC has reviewed and accepted the licensee's report. It is assumed that the licensee's report would be submitted in advance of the planned date for initiating the activity, so that delays in planned activities would be minimized in implementing the hold point.

A major goal in developing the concept of hold points in the construction process would be to gain prospective assurance of licensee compliance in the implementation of the QA program in the period between the CP and the OL. Hold points could be established whenever a construction milestone is identified which requires the initiation of a new major activity such as installation of electrical cable, pouring of concrete, and installation of primary piping.

Hold points could also be established when there is a major change in the mix of QA personnel or a major change in QA organization and management. The following nine hold points, of which four are already established, are presently being considered and under review: (1) the LwA,* (2) the CP,* (3) the start of concrete and steel construction, (4) the start of installation of electrical cable, (5) the start of the installation of the primary coolant pressure boundary, such as pressure vessels and piping, (6) before preoperational testing, (7) before initiation of hot functional testing, (8) before fuel loading at the issuance of the low-power OL,* and (9) at the issuance of the full-power authorization.*

The new hold points, numbers (3) to (7), have been identified at this point merely as candidates for hold points. With the development of the concept of hold points, these and/or other hold points may be determined to be appropriate candidates.

- Implementation of the hold point concept will be pursued with IE, NRR, the Regional Offices, and ELD in evaluating the practicality of the various milestones considered. It may be a relatively simple procedure to add hold points (3) to (7) to the CP in the form of conditions of the construction permit or a more time-consuming rule change to NRC regulations may be required. Additionally, major effort will be required to identify the details of what constitutes acceptance and what criteria are to be evaluated at each hold point.

- The following are examples of current practices which include a form of certification and, to some extent, represent current application of some of the concepts envisioned for hold points. One example of a current practice which resembles the hold point concept is the review of QA implementation in the Licensee Contractor and Vendor Inspection program. Region IV inspects the implementation of QA programs of nuclear steam supply system designers and architect/engineer (A/E) firms which have been submitted to and approved by NRR in the form of Topical Reports or Standardized Programs. Upon completion of inspections confirming satisfactory implementation of QA programs, NRC issues a confirmatory letter to the nuclear steam system supplier or A/E firm which indicates the NRC satisfaction with the implementation of the QA program.

*Indicates current NRC regulatory hold point.

The NRC confirmatory letter also states:

> Continuing acceptability of implementation of your QA program is contingent upon your maintaining a satisfactory level of program implementation, certified through periodic NRC inspection, throughout all corporate organization units and nuclear projects encompassed by your program. Should your program implementation at any time be found unacceptable you will be notified by letter and requested to correct the deficiencies promptly. In the event you fail to correct ... the applicant and licensee ... will be notified that the generic implementation of your program is no longer acceptable to the NRC.

This paragraph in the confirmatory letter addresses, in part, a prospective evaluation of the vendor's QA program.

Another example of current practice is the ASME-administered certification of manufacturers of pressure boundary components (pressure vessels, pipes, valves, pumps, etc.) via the ASME/NB accreditation (N-stamp) program. It differs from the vendor inspection program in that a third party, ASME, provides the certification that the vendor's QA program requirements are met. This process of accreditation of vendor capability is accepted worldwide, and allows the NRC, as well as licensees to devote limited inspection effort to these areas. The ASME program illustrates the possibility of using a qualified third party for the evaluations and certifications associated with a new hold point system.

The United Kingdom (UK) practice employs three types of hold points that are controlled by the Nuclear Installation Inspectorate (NII) which regulates construction and commissioning of nuclear power plants. The construction permit includes license conditions that provide for three types of direct actions by the NII. These actions are: (1) the requirement for a "Consent," which essentially prevents the licensee from carrying out a specific operation on the site unless the NII agrees; (2) the "Approval" procedure, which requires the licensee to furnish its procedure for carrying out a specific activity to NII for approval (applicable to all prospective QA requirements and testing arrangements); and (3) "Direction" (used rather infrequently), which directs the licensee to carry out an operation the NII considers essential in the interest of safety. The implementation of these hold points depends on very capable resident inspectors (and their staffs) and on the full cooperation of the licensee.

The examples of hold points, briefly discussed so far, differ in part from the present practice of NRC's construction inspection program. The present inspection program focuses on review of quality assurance procedures and records, direct observation of work in progress, and completed work for the purpose of assuring compliance with regulatory requirements. Assurance is obtained by the absence of significant noncompliance in the area inspected. In contrast to this program, this discussion of hold points focuses on review based on performance and a prospective review of the capability and readiness of the licensee; in other words, on management's commitment to the establishment of an effective organization staffed with qualified manpower, supported by appropriate equipment and detailed procedures.

As a result of the recent difficulties experienced at some construction sites it should be clear to the industry that it would be in their best interest to have a viable, effective, and responsive QA organization at all times. INPO's self-evaluation program is moving in this direction. New NRC requirements for hold points, as suggested above, could be promulgated by rule change or contained in certain conditions of the CP and would provide the incentive to the licensee to establish a viable, effective and responsive QA organization. A deficiency finding at any of the newly considered hold points between the CP and the OL would not necessarily stop the ongoing construction, but would primarily affect the initiation of a new construction phase. It may be in the best interest of the licensee to ensure that this new phase in the construction program will meet the NRC requirements for QA compliance before initiating the activity.

Review Points

For the purpose of this paper, review points refer to the milestones selected for the conduct of an integrated and documented review by the NRC to retrospectively assess the demonstrated implementation of the QA programs since the last review point, and to prospectively appraise the capability of the licensee and the licensee's contractors to continue. Review points contrast with hold points in that the review point is a periodic review (perhaps annually) while the hold point is an evaluation and decision point that occurs only at designated milestones in a plant's construction.

The frequency of review points could be on an annual basis, like the annual SALP evaluations, or the review points could be tied to the percent completion of construction. A disadvantage of selecting review points on the basis of percent completion is that the elapsed time between review points may vary significantly,

depending on the licensee's commitment (or lack thereof) to expedite construct or. In such a case, the review points may be too frequent or too far apart to serve a meaningful purpose.

In many respects, the SALP program has similar objectives to those identified for review points. SALP program objectives (reference NRC Manual Chapter 0516) are as follows:

- Identification of unacceptable licensee performance;
- Improvement of licensee performance;
- Improvement of NRC inspection program;
- Rationale for NRC's allocation of manpower;
- Achieving regional consistency from a national perspective.

The SALP assessment is intended to be sufficiently diagnostic to provide a rational basis for allocating NRC resources and to provide meaningful guidance to licensee management.

SALP does not apply to QA alone but attempts to assess the overall performance of the licensee on an annual basis. The SALP program as presently structured is primarily a retrospective evaluation. SALP has no prospective component for QA. The staff is pursuing the idea of expanding the scope of the SALP program to include a prospective review of the licensee's capability and readiness such that an expanded SALP program could serve as the review point being considered in this study.

Acceptance Points

For the purpose of this paper the term acceptance point incorporates retrospective verification that a certain activity, structure, system, or component has been completed in accordance with applicable QA program requirements. In practice, acceptance points would be comparable to present quality control activities. Acceptance of a product or process by a licensee's inspector can be viewed as a form of certification. For example, typical acceptance points may include a check on rebars and forms before pouring concrete, the installation of a piece of equipment that had to be qualified under specified conditions, or a modification of a pipe-run that required approval by design review. It is generally recognized that for any continuing process, like the construction of a nuclear power plant, quality engineering selects many such acceptance points, often running into the thousands, to assure that the finished product meets all the requirements. The focus of evaluation at these points is retrospective and is on quality control activities rather than on quality assurance per se.

The reason for considering the concept of acceptance points is to provide increased confidence in the quality of construction. Many activities, for example, the placement of reinforcing bar, have a very small window for the opportunity to verify correct placement. The licensee is expected to have available a sufficient number of qualified QC personnel to sign off on the many acceptance points during the progress of construction and testing. It is not possible for the NRC to match this organization at any one site, and even less so on every construction site. As a result, NRC's present practice of construction inspection, can only hope to audit a judicious sample of the many acceptances.

It is because of the magnitude of the inspection task that the concept of a designated representative, as employed by the Federal Aviation Administration (FAA), has attracted the staff's attention. Enclosure 2 of this Commission paper addresses this concept in greater detail, especially as it applies to verification and certification of acceptance points. If the staff were to restrict the study of acceptance points to quality assurance activities, rather than to the much more numerous quality control activities, it would be more difficult to employ designated representatives. The reason is that a DR would not be expected to make subjective determinations as would be required for QA activities, but merely be expected to verify and certify the acceptability of activities or products to specific criteria.

DESIGNATED REPRESENTATIVE PROGRAM

Background

The Federal Aviation Administration (FAA) utilizes a system of designated representatives (DR) to act for the FAA in the examination, inspection and testing necessary for the issuance of aircraft certificates by the Administrator. Nominees meeting the requirements for appointment are authorized to represent the FAA in determining the compliance of aircraft, aircraft components and their repair or alterations with the requirements of the FAA's regulations. The DR serves as a direct agent of the FAA in the performance of certification duties and is guided by the same quality assurance requirements, instructions, procedures, and interpretations as FAA employees in the performance of their certification duties. During the time the DR performs certification duties for the FAA, salary and employment benefits continue to be provided by the representative's full-time employer.

The FAA does not maintain an engineering staff in sufficient numbers to review all the details associated with the design of an aircraft. However, the agency must be certain that each design for a new aircraft meets all the regulatory requirements. To meet this commitment the FAA depends on the resources provided by aircraft company employees called Designated Engineering Representatives (DERs) who review engineering reports, drawings, and data to ensure compliance with all aspects of the regulations on behalf of the FAA. During the design of an aircraft, the DER acting for the FAA will certify design compliance with the FAA's regulations. The DERs are usually senior engineers, employed by the manufacturer, who possess detailed knowledge of the design, based on a daily involvement that is not practical for FAA personnel to achieve.

Once the FAA awards a Production Certificate for an aircraft, government oversight of production is maintained by a system that couples direct FAA review by assigned inspectors with the work delegated to Designated Manufacturing Inspection Representatives (DMIRs). The DMIRs certify, on behalf of the FAA, that aircraft and/or components are manufactured consistent with the approved design and specifications. Upon final inspection, Airworthiness Certificates are issued for each aircraft and can be issued under authority delegated to the DMIRs. DMIRs are individuals who have many years of experience in manufacturing, special processes and inspection and have been found to be qualified by the FAA.

The certification process employed by the FAA uses a series of hold points. The design and manufacturing processes proceed to specified hold points where the review and acceptance determinations are made by the FAA in order for the

process to continue. During the past few decades, as the aviation industry increased in size and technical complexity, large manpower demands were placed on the FAA to provide more inspectors to meet the increased inspection demands. Delays in the manufacturing process caused by not having an inspector available when needed are expensive to the manufacturer. Implementation of the DR program provided the FAA with an immediate increase in the number of qualified inspectors. The aviation industry readily accepted the DR program since it was financially beneficial to the industry to have available a qualified person who could represent the FAA when needed. The FAA's DR program continues to be an indispensable technique in assuring that aircraft are designed and manufactured in accordance with the rules and standards set forth in FAA regulations.

A recent study by the National Academy of Sciences, entitled "Improving Aircraft Safety, FAA Certification of Commercial Passenger Aircraft" (Washington, D.C. 1980), investigated the DR program employed by the FAA. The study concluded that, given the thousands of drawings, calculations, reports and tests that the FAA must be certain meet applicable requirements, the designated representative program which augments the capability of the FAA to review and certify the aircraft design and production, is not only appropriate but indispensable. The National Academy of Sciences study also found that the designated representative position is a sought-after assignment. The DRs generally hold key technical or supervisory positions in private firms and typically have 15-20 years experience. The study observed that the individual appointments evidently contributed to a high degree of dedication and motivation in the individual's performance. This motivation is apparently based on a number of factors including peer recognition in being selected, special salary scale, and better promotion potential.

One negative aspect of the DR program is the question or concern that can be raised that the licensee's employees are regulating the licensee - a "fox guarding the chicken coop" perception. Close scrutiny and audit of the program and DR personnel would be required to ensure that this form of self-regulation works.

NRC Programs

In early 1982, IE staff met with representatives of FAA Headquarters (Washington, D.C.) and FAA New England Regional Office (Burlington, MA) to discuss the FAA DR program and to see how a DR program concept could be applied to NRC activities. Visits were also made to two private firms which are regulated by the FAA and employ Designated Manufacturing Inspection Representatives.

The general guidelines and qualifications for a DR to be used by the NRC would be similar to those presently used by the FAA. A preliminary listing of guidelines and qualifications is given below:

GENERAL GUIDELINES FOR NRC [illegible]

1. Qualifications. NRC would establish background and [illegible] for each technical area. The licensee and/or contractor would [illegible] list of personnel meeting NRC's requirements for each [illegible] would select personnel from that list.

2. Term of Duty. NRC would issue appointments for a period of two years. Satisfactory performance and continued need of service would result in NRC renewal of the appointments in two year increments. Unsatisfactory performance or personal request by the DR would result in termination of the appointment at any time.

3. Supervision. The Senior Resident Inspector (SRI) would supervise the DR when the DR is carrying out NRC responsibilities. It is [illegible] the DR would spend a fraction of his/her time carrying out NRC [illegible] In the absence of the SRI, the DR would be supervised by the [illegible] Regional Section Chief.

4. Training. Before performing any work as a DR for the NRC, the DR would receive a specified amount of training. The training and orientation for each DR would be standardized.

5. Salary. For the period of time the DR is performing in assigned capacity, pay and benefits would be continued by the DR's full-time employer. Overtime and holiday pay would also be the same as stipulated by the working agreement with the full-time employer. A special salary scale (for example, an additional 5 percent salary increase) may be appropriate in recognition of the importance of the DR position to the licensee's staff.

6. Reporting and Decision Making. Results of inspection efforts would be given to the SRI for inclusion in SRI inspection reports. Any items of non-compliance would be reported to the SRI for [illegible] It is not the intent of this program to put the DR in a situation of conflict with the full-time employer, but rather to allow the NRC to utilize the objective results of the DR's expertise.

Implementation of a DR program would require an amendment to the Atomic Energy Act and revisions to the NRC regulations. The legal ramifications of the DR program are presently being studied. The staff conservatively estimates that it would require a minimum of three years to develop and write the necessary legislative changes, submit the changes for congressional approval, write and issue the new regulations, and select and train personnel to perform as designated representives. Within that time frame, most plants currently under construction would have received an operating license. This long time period to implement the program will negate its use for those plants under construction, but the program could be applicable to future plants and possibly to operating plants.

Acceptance Points and Designated Representative

Enclosure 1 discusses the concept of establishing certain acceptance points during the construction phase of nuclear power plants as a means of increasing NRC's confidence in the quality of construction. If the NRC were to verify and certify acceptance points, a large increase in resources would be required. Delays in providing an NRC inspector to verify the acceptance points could be costly to the licensee. Implementation of a program utilizing NRC's designated representatives could provide the required NRC verification of acceptance points without a major increase in present NRC staffing levels. Since the DR could verify and certify acceptance points for both the NRC and the licensee at the specific time an activity has been completed, delays in the licensee's process should be minimized assuming the specific activity has been correctly completed.