

August 31, 1987

POLICY ISSUE

SECY-87-220

For- The Commissioners (information)

From- Victor Stello, Jr. Executive Director for Operations

Subject: ASSURANCE OF QUALITY

Purpose: To inform the Commission of the staff's shift in emphasis from 'compliance-based' inspections of licensee's quality verification organizations to "performance-oriented" inspections of these organizations.

Background: In May 1984, the staff issued NUREG-1055, 'Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants.' NUREG-1055 identified poor management as a major contributor to quality breakdowns. The report also addressed issues that went beyond traditional quality assurance (QA) issues and focused on (1) steps that could be taken in licensees' QA programs and (2) changes in the NRC oversight of such programs to improve the performance of the line organizations ("quality achievers") and the licensees' QA organizations ("quality verifiers"). Traditionally, a licensee established a QA program that was reviewed and accepted by the NRC; the NRC then "inspected" the implementation of the licensee's programs. These inspections were heavily oriented towards programmatic reviews rather than reviews of actual day-to-day work in progress or actual plant hardware.

The Commission, in a December 12, 1985 response to Congress involving the Issues raised in NUREG-1055, made it clear that it is the responsibility of licensees—not the NRC—to achieve and assure quality. The Commission indicated that improvements in quality must come from the industry itself, and that the key to achieving quality and assuring quality lies in line management. Therefore, the Commission concluded that the NRC programs for improving quality should focus on the ability of licensee management to ensure that significant safety problems are either prevented or detected early and adequately resolved.

Discussion: In the three years since the completion of NUREG-1055, many of the NRC programs it generated to focus on the performance of line management have been completed or are ongoing. Because the majority of the NRC's regulatory oversight and inspection activity is aimed at monitoring the performance of the licensee's line organization in achieving quality, most of these programs were initiated in NRC organizations outside of the NRC Quality Assurance Regulatory Programs. These include, for example, the development of performance indicators and improved diagnostic inspection techniques. Therefore, with most of the agency's focus on the line organization, it is now appropriate for the NRC Quality Assurance Regulatory Programs to focus principally on initiatives aimed at evaluating the effectiveness of the quality verification organizations in identifying, reporting, and ensuring the correction of significant safety problems.

As a result of the recent NRC reorganization, the Office of Nuclear Reactor Regulation (NRR) Quality Assurance (QA) Branch is responsible for developing and implementing a comprehensive program for assuring quality and reliability of reactor licensee facilities. These activities were responsibilities of the former Office of Inspection and Enforcement (IE) QA Branch. Other responsibilities of that Branch were transferred to the Offices of Nuclear Materials Safety and Safeguards and Research. These discussions are limited to those functions transferred to the NRR QA Branch. The major emphasis of this branch is now on reactor operations. Thus, the staff believes it is crucial that NRC Quality Assurance Regulatory Programs be oriented to evaluating the implementation of licensees' quality verification programs in the identification and correction of safety-significant technical problems, in addition to merely evaluating the processes of licensees' quality assurance programs. Further, because there are essentially no new plants being licensed, the role of a licensee's quality verification program has shifted from one of developing and monitoring programs to oversee contractors to one of being a more integral part of the licensee management feedback loop. Consequently, repetitive reviews of licensee's quality assurance programs that have been in place for some time would not be an appropriate use of NRC's limited resources.

Quality verification is synonymous with systems of checks, audits, inspections, and other forms of verification performed by a licensee's Quality Assurance organization, the Quality Control organization, the Quality Engineering organization, and/or other independent review organizations such as a Plant Operations Review Committee and Safety Operation Review Committee. These organizations monitor the overall performance of the line organization and are responsible for ensuring that quality is achieved and that significant problems are avoided.

These organizations—in particular—the Quality Assurance organization—must have the ability to understand significant operational safety problems and be technically credible to ensure that NRC requirements are satisfied. It is imperative that licensees' verification organizations understand reactor operations and plant systems, and that they be involved in the day-to-day operations in the plant. Monitoring processes in a program review cannot be a substitute for the actual observation of safety-significant activities. The NRC staff expects the staffs of licensees' verification organizations to consist of qualified professionals who:

- (1) Routinely monitor Control Room decorum and behavior, including monitoring of back-shift activities.
- (2) Understand fundamental engineering concepts and design analyses as the concepts/analyses relate to plant system functions.
- (3) Recognize the interrelationship of plant systems and components, and understand how the systems/components function.

Further, in addition to their technical capabilities, the staff also expects verification organizations to be performance oriented so they have the capability

to identify, report, and ensure the correction of safety-significant problems. As such, the staff emphasizes that quality cannot be inspected or audited into a work product. The assurance of quality rests with the line organization responsible for the work product/function. In this regard, verification involves the use of technically knowledgeable staff to provide feedback to line management. It is not acceptable for licensees to rely solely on the existence and audit capability of a QA/QC organization for verifying quality. In this regard, there are many indicators that licensees can use in determining the extent to which line managers rely on QA/QC for assuring quality. For example, the effectiveness of corrective actions in resolving previously identified problems is a measure of properly dealing with the root cause.

The staff has recently completed the first inspection initiated by the NRR QA Branch to assess the effectiveness of licensees' quality verification organizations. Temporary Instruction 2515/78, "Inspection of Quality Verification Functions," describes the inspection guidance for focusing on the performance of quality verification organizations. The techniques assess whether quality verification organizations are, in fact, providing licensees with an effective and independent internal problem-detection capability. Further, the staff expects to determine whether quality verification organizations are given adequate technical resources and support from management, whether management really relies on quality verification organizations to evaluate its operations technically as well as procedurally, and whether line management is taking corrective action on safety-significant Issues raised by the quality verification organizations.

This type of inspection technique accomplishes two significant goals. First, it sends a clear message to the industry that the NRC expects licensees' quality verification organizations to be technically credible with the understanding necessary to monitor reactor operations. Second, it places the emphasis of NRC inspections on technical, safety-significant issues rather than on QA programmatic reviews. This sends a clear message to the industry that the NRC is aggressively pursuing technical issues.

The staff in no way means to imply that the NRC does not consider programmatic inspection processes important; it is the focus of the inspection process that must be changed. The "performance-oriented" inspection technique focuses on significant safety problems first. Programs are then reviewed to evaluate deficiencies and to determine the effects on the safe operation of the facility.

Further, the staff in no way means to imply that "performance-oriented" inspections de-emphasize the importance of enforcement. Strong enforcement actions must be taken when significant violations of NRC requirements are identified. The staff believes that, although these types of inspections may be viewed as more subjective since the areas and scope of inspection can vary from site to site, they will result in improved enforcement actions that focus on the underlying causes of identified violations of NRC requirements. By focusing on performance of the quality verification organizations, the staff can better evaluate the significance of technical issues identified by the quality verification

organizations and the ability of the organizations to communicate these issues to line management, and ensure effective resolution.

This reorientation of NRC inspection efforts requires training and increased interface with regional inspectors, by NRC managers, and NRC staff. An upgraded QA training course is being developed to replace the one put in place following the Ford Study. It is being structured for a broader technical audience. The course will feature lessons learned from studies such as the Ford Study, and it will have as one of its major objectives improved staff assessment of licensees' quality and quality assurance programs through technical inspections. The staff intends to proceed to implement the shift in emphasis in the assurance of quality program described above.

[Original signed by]

Victor Stello, Jr.

Executive Director for Operations