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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

September 23, 1980

Docket Nos. 50-295
and 50-304

Mr. J. S. Abel
Director of Nuclear Licensing
Commonwealth Edison Company
Post Office Box 767
Chicago, Illinois 60690

Dear Mr. Abel:

We have completed our reviews of your letters dated May 15 and June 9, 1980 in response to our letters dated April 8 and May 20, 1980. This correspondence related to our re-evaluation of the Quality Assurance (QA) Program for Zion Station.

Our review was initiated by Item F.1(f)(8) of the Task Action Plan for Indian Point and Zion sent to Commonwealth Edison Company in our letter dated April 8, 1980 from Mr. Harold Denton to your Mr. Cordell Reed. We also held a meeting with your staff on June 5, 1980 to discuss your responses to our previous requests for information. Our requests were based primarily on the need for an upgraded QA Program and the QA procedural controls for Zion Station. Our analysis of the TMI-2 QA Program and QA procedural controls has indicated a need for upgrading.

As a result of these activities a request for additional information and staff positions #43 - 51 are provided in Enclosure 1. We request your response within 30 days of receipt of this letter. In addition, we have developed other staff positions presently applicable to Zion 1 and 2, and Indian Point 2 and 3. Also, we request your response to the positions of Enclosure 2 within 30 days of receipt of this letter. We request your commitment to the positions of Enclosures 1 and 2 and your proposed implementation schedule as a part of your 30 day response. As has been our policy, you may provide alternative specific proposals supported by adequate bases for our review and evaluation in lieu of the staff positions.

In closing, as noted during the June 5, 1980 meeting, we propose a meeting at Zion Station for further discussions. The meeting is proposed at your convenience shortly after our review of your responses to Enclosures 1 and 2.

The meeting's purpose would be (1) to discuss your new proposed QA Program for corporate headquarters and for the plant site, (2) to discuss the program with cognizant corporate personnel and other supervisory QA personnel responsible for implementing and overseeing the QA Program, and (3) to finalize our re-evaluation of the upgraded QA Program. We propose to expedite our review of your responses and to be ready to meet with you and your staff during November 1980.

Sincerely,

Steven A. Varga, Chief
Operating Reactors Branch #1
Division of Licensing

Enclosures:
As Stated

cc: w/enclosures
See next page

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ENCLOSURE 1

Staff Positions/Request for Information
Zion Units 1 & 2
Quality Assurance Program Re-evaluation

43. It is the staff position that all items including programmatic requirements (e.g., emergency plan, security, meteorology, etc.) affecting safety that can be derived from the General Design Criteria of 10 CFR Part 50 Appendix A and other pertinent regulations shall be under the control of CECo's 10 CFR Part 50 Appendix B quality assurance program. These items include those that can be identified from Regulatory Guide 1.29 (positions 1 through 4) plus spare and replacement parts, and consumables and expendables needed for the various activities performed in connection with those items. The current "Q-list" (Appendix 1 of the answer to Zion Station Question 1.5) should be expanded to meet this staff position. (See item A of Enclosure 2.)

44. It is the staff position that

    a) independent inspections, verifications, and surveillance activities (Tech Spec and QA) be performed by CECo QA to the extent necessary to assure the correctness of activities such as procurement, QC inspection, startup, shutdown, maintenance, modification, repair, replacement, and testing. (See item D of Enclosure 2.)

    b) independent surveillance activities should not be limited to those "required by the technical specifications" as indicated in the first paragraph of the response to item 5b. The quoted words should be deleted.

    c) procedures, instructions, and checklists discussed in the response to item 5 have the documented concurrence of CECo QA. (See item E of Enclosure 2.)

45. It is the staff position that QA coverage be scheduled for activities requiring off-shift quality verification. (See item C of Enclosure 2.)

46. It is the staff position that the Director of Quality Assurance and the Quality Assurance Supervisor (Maintenance) meet the experience requirements of Section 4.4.5 of ANSI/ANS-3.1-1978. (See item C of Enclosure 2.)

47. It is the staff position that maintenance instructions should be included in the response to item 17 and that maintenance instructions and all testing procedures should have documented concurrence of CECo QA. (See items D and E of Enclosure 2.)

48. Your response to item 18 does not clearly indicate that engineering approval and Station Nuclear Engineering Department approval of design or design changes satisfy the design verification requirements of ANSI N45.2.6. Provide a commitment that a) a design or design change is not released prior to such verification or b) the controls of item 18 are applied.

49. Your response to item 35 should also describe the criteria established by CECo to evaluate the validity of suppliers' certificates of conformance.

50. The Zion QA program should comply with later versions of Regulatory Guides than those listed in CE-1-A and additional Regulatory Guides as follows:

    a) 1.26, Rev. 3
    b) 1.28, Rev. 2
    c) 1.29, Rev. 3
    d) 1.144 (1/79)

51. The responses to our series of questions are documented separately from the Zion FSAR and CE-1-A. Incorporate or reference all responses to these QA questions, including the positions in Enclosure 2, in the FSAR or CE-1-A to provide a unified QA program description.

ENCLOSURE 2

Regulatory Staff Positions - Generic

The licensee is requested to address the following staff positions or describe equivalent alternatives for staff evaluation. The response should also indicate the schedule for implementation.

A. Extension of the QA Program to All Items Affecting Safety

It is the staff's position that the listing (Q-list) of structures, systems, components, and other safety aspects (e.g., meteorology, plant security) to which the Appendix B to 10 CFR Part 50 Quality Assurance (QA) program applies shall be expanded to include all items affecting safety. These items can be derived from the General Design Criteria given in Appendix A (to 10 CFR Part 50) and from other pertinent regulations, and include Regulatory Guide 1.29 (positions 1 through 4) plus spare and replacement parts, and consumables and expendables needed for the various activities performed in connection with those items. The operational QA program would then be applicable to all future activities (backfit not required) conducted in connection with these items such as maintenance, modification, repair, performance testing, surveillance testing, and replacement. As required by Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50, the QA program shall provide control over all activities affecting the quality of the identified items to an extent consistent with their importance to safety. In this regard, the extent of applicability of the 18 criteria of Appendix B and related requirements given in the SRP, Regulatory Guides, and endorsed standards to a specific item shall be determined by the licensee through a technical evaluation conducted by Engineering and QA. It is not the intent of this position to modify in any way the design requirements applicable to an item added to the Q-list, but rather to assure, through appropriate QA controls, that the specified design requirements and subsequent activities for an item, are properly implemented.

B. Organizational Independence of QA/QC (Operations Phase)

It is the staff's position that the QA organization responsible for the onsite QA activities shall be located onsite and shall perform QA review, inspection, surveillance, and audit functions. The QA organization responsible for the onsite QA activities shall report technically and administratively to offsite QA management but shall maintain close communication ties with the Plant Superintendent and his staff. Personnel responsible for performing the independent inspection and verification functions and the review and approval of quality-related procedures shall report technically and administratively to the QA organization unless special situations warrant otherwise. Situations of this kind along with a commitment that the QA organization will be responsible for authorizing and controlling them shall be identified and documented as part of the QA program, and submitted for staff review and evaluation.

C. QA Staffing and Qualification Requirements

The licensee is requested to describe the number of onsite/offsite QA/QC personnel including the basis for determining the QA and QC staff size, specific tasks they

are responsible for performing, and the level of qualification and certification required for the assigned tasks. Staffing levels should include provisions for augmentation during peak periods of maintenance, modification, refueling, or inservice inspection. Adequate QA/QC staffing and coverage for specific assignments shall be based on projected plant work loads through coordinated meetings with plant staff and QA organization and by QA attendance at daily plant staff meetings involving discussions of daily and projected plant work loads.

Educational/training aspects to be considered relative to the qualification and certification program include a degree in engineering, certified professional engineer in QA, certified ASQC-QA engineer, or a related science, military, vocational or apprenticeship training, or on-the-job training. In addition, an introduction and training and qualification program should be established such that:

a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, procedures, regulatory guides, standards, and codes.

b. Personnel responsible for performing inspections, examinations, and tests are trained in the principles, techniques, and requirements of the activity being performed and meet Regulatory Guide 1.58.

c. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria developed to determine if an individual is properly trained and qualified.

d. Certificates of qualifications clearly delineate the specific inspection and quality-related functions personnel are qualified to perform including the criteria used to determine qualification.

e. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining and/or recertifying as determined by management or program commitment.

f. For formal training programs, documentation includes the objective, content of the program, attendees, and date of attendance.

QA/QC personnel are also expected to be familiar with or knowledgeable in the areas affecting quality appropriate to their assignments such as:

a. Appendix B to 10 CFR 50

b. Control room operations

c. Instrumentation and calibration control

d. Plant chemistry/laboratory practices

e. Maintenance, modification, and repair

f. Radiation

g. Security systems

h. Concrete practices

i. Technical specifications

j. Electrical systems

k. Mechanical systems

l. Fuel handling/waste reprocessing

m. Welding, NDT, special processes

n. Safety, fire, and emergency systems and programs

o. Piping codes and standards

D. Involvement of QA Organization in Operational Activities

The QA organization, both onsite and offsite, should be actively involved in all aspects of the operation of a nuclear power plant that affect safety. The extent of involvement, as determined by the licensee's technical and QA staff, is dependent upon the specific activity and its subsequent effect upon plant safety and reliability and the complexity of the QA requirements that are involved. Responsibilities of the QA organization should include the following:

a. Surveillance and verification of pre-operational, startup, and operational tests, maintenance, modifications, and quality activities associated with satisfying technical specifications and inservice inspection and testing.

b. Review of procurement documents and inspection of received items.

c. Training and indoctrination of plant personnel responsible for performing quality-affecting activities in the QA administrative program controls.

d. Surveillance and verification to assure that instrument calibration programs are conducted in accordance with procedures.

e. Control of the inservice inspection program.

f. Active involvement (e.g., frequent visits to the plant site) by the offsite QA Manager to monitor the implementation of the QA program and to assist in the resolution of quality-related problems.

g. Participation by the onsite QA/QC personnel in daily staff meetings (e.g., operation, maintenance, and modification) associated with planning the work and schedules for the plant to assure proper QA and QC staffing levels and quality-related procedures for all operational activities.

h. Performing an overall assessment of the effectiveness of the QA program which involves developing and evaluating trend analysis, and promulgating and modifying QA policies and procedures as necessary.

E. QA Involvement in the Review/Approval of Documents Affecting Safety

It is the staff's position that qualified individuals in the QA organization, either onsite or offsite, shall be responsible for performing reviews of documents affecting safety, including changes thereto. Documents subject to QA review shall include, but not be limited to, the following: administrative directives and procedures addressing operations, maintenance, technical specifications, inservice inspection and testing, modification, calibration, testing, fuel handling, and procurement; design change notices; drawings; specifications; and nonconformance and corrective action reports. Each document should be reviewed to a depth sufficient to assure that applicable QA requirements (e.g., the necessary inspection requirements, final documented verification of implemented procedures and check lists, methods, and acceptance criteria) have been identified and specifed therein. Evidence of the review shall be documented by approval of the QA reviewer.