Commonwealth Edison
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Address Reply to: Post Office Box 767
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October 17, 1980

Mr. Harold R. Denton, Director
Office of Nuclear Reactor Regulation
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Subject: Zion Station Units 1 and 2
Response to NRC Request for
Information for Quality
Assurance Program - Upgrade Review
NRC Docket Nos. 50-295 and 50-304

Reference (a): April 8, 1980, letter from
A. Schwencer to D. L. Peoples

(b): May 20, 1980, letter from
S. A. Varga to D. L. Peoples

(c): September 23, 1980, letter from
S. A. Varga to J. S. Abel

Dear Mr. Denton:

Reference (a) requested Commonwealth Edison Company to provide information for the NRC Staff to perform a QA Program - Upgrade Review for Zion Station. Reference (b) requested additional information to supplement the material submitted in connection with Reference (a). Reference (c) likewise requested additional information to References (a) and (b). Commonwealth Edison's response to this request is contained in the Attachment to this letter.

Please address any question that you might have concerning this matter to this office.

One (1) signed original and thirty-nine (39) copies of this transmittal are provided for your use.

Very truly yours,

J. S. Abel
Director of Nuclear
Licensing

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

SEP 29 RECD
WFN

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.

NRC Docket Nos. 50-295
50-304

ATTACHMENT 1

Commonwealth Edison Company Response

to

NRC Staff Request for Information

for

Zion Station Units 1 and 2
Quality Assurance Program - Upgrade Review

RESPONSES TO NRC's QUESTIONS (Cont.) 43-51 AND NRC
REGULATORY STAFF POSITIONS - GENERIC REGARDING
COMMONWEALTH EDISON COMPANY
QUALITY ASSURANCE PROGRAM FOR ZION UNITS 1 & 2

Question #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.)

Response:

As provided in Topical Report CE-1-A, Page 2-6, Rev. 14, the Quality Assurance Program applies to safety-related and ASME Section III activities and items and related consumables plus fire protection, security, emergency plan, meteorology and radwaste shipments. Also, the Program applies to the control of spare parts and replacement parts as provided in Section 7 of Topical Report CE-1-A. The response to NRC Question #1 covers the commitment to Regulatory Guide 1.29. Also refer to the response to Item A of NRC Staff Position of Enclosure 2 relative to applying the CECo Quality Assurance Program to work and items identified as reliability-related.

Item A Staff Position of Enclosure 2

A. <u>Extension of the QA Program to All Items Affecting Safety</u>

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 theAAppendix 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 modigy 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.

Response:

Commonwealth Edison can not commit at this time to complying with Item A of Enclosure 2 of NRC's Regulatory Staff Positions concerning extension of the Quality Assurance Program to all items affecting safety. At the present time, there is no definition by NRC of which items in the plant are to be considered as affecting safety. Furthermore, according to NUREG-0660 Volume 1 - NRC Action Plan Developed as a Result of the TMI-2 Accident, the identification of the items in the plant which are to be considered as affecting safety is to be established by NRC in 1983. It states that NRC will develop guidance for the expansion of the listing of equipment important to safety and later for what constitutes activities acceptable for effective quality assurance programs for design, construction and operation. Also, it is our understanding that rule making has been proposed on this subject. Lacking the definition or listing by NRC of such items to be specifically covered by the Quality Assurance Program and until such time as the rulemaking hearings have been held and finalized on expanding the Quality Assurance Program to include items affecting safety, commitment to this NRC position prior to resolution of the above two matters does not appear to be an appropriate approach at this time. Furthermore, Commonwealth Edison has performed a mini WASH-1400 study of the Zion Units 1 and 2. This study concludes that Zion does not represent a risk greater than other nuclear power plants located at other sites. This study will be confirmed by a more detailed study, which will be submitted to NRC by February 1981. Commonwealth Edison feels that this expanded study will confirm the results of the WASH-1400 study and therefore, the measures being suggested to meet new Quality Assurance Requirements are not required on an expedited basis at Zion.

As an alternate to the approach of the NRC Staff position, it is proposed that NRC accept our currently implemented "reliability-related" concept for application of the Corporate Quality Assurance Program to other items and work in the plant.

As explained in the responses to NRC questions #4 and #3, the concept is that plant work and items not identified as safety-related but that could have affect on plant reliability and/or personnel and plant safety if something went wrong, are identified as reliability-related by Engineering, Operating, Maintenance, and Technical Staff personnel, verified by Quality Control and assured by Quality Assurance under the control and requirements of the Corporate Quality Assurance Program. The response to NRC Question #1 covers the commitment to Regulatory Guide 1.29.

Question #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.)

Response:

The independent inspections, verifications and surveillance activities (Tech Spec and QA) are performed by qualified CECo QA personnel under the requirements of the Quality Assurance Program to the extent necessary to assure the correctness of the activities such as procurement, QC inspections, startup, shutdown, maintenance, modification, repair, replacement and testing.

Item D Staff Position of Enclosure 2

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 offiste 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 achedules 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.

Response:

The involvement of the QA organization in operational activities include the following responsibilities listed in Enclosure 2 - Regulatory Staff Positions - Generic which have been explained in the responses to the previous NRC questions related to these responsibilities.

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. Administration of the inservice program is assigned to the Technical Staff. QA personnel assure that the requirements of the Inservice Inspection Program are met and verify that the results are acceptable.

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.

Question #44

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.

Response:

The first paragraph of the response to Question 5b should read as follows:

> The results of inspections, verifications and surveillance activities are filed in accordance with station procedures and maintained in accordance with the Technical specification requirements.

Question #44

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.)

Response:

The procedures, instructions and checklists discussed in the response to item 5 are required under the CECo Quality Assurance Program to have the documented concurrence of CECo QA. Also see response to NRC Question 17 which provides a table which identifies organizational responsibilities for the preparation, document review, concurrence, and/or approval of documents affecting safety.

Item E Staff Position of Enclosure 2

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

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 checklists, methods, and acceptance criteria) have been identified and specified therein. Evidence of the review shall be documented by approval of the QA reviewer.

Response to Item E Staff Position of Enclosure 2:

Zion Station procedures and other documents affecting safety, including changes thereto, covering activities at the station are reviewed by qualified station personnel and are required to be reviewed and approved by the On-Site Review Group as to being acceptable for use in the station. Also see response to NRC Question 5(f). QA is responsible for assuring that these procedures and other station documents affecting safety include, as appropriate, necessary quality requirements, have been reviewed by qualified personnel and have been reviewed and approved by On-Site Review as to being acceptable for use in the plant. QA performs this responsibility by direct review and approval, by surveillance and by audit. The QA review by surveillance and audit covers administrative, operations and departmental type procedures. Specific review and approval by QA is required of documents affecting safety involving maintenance, in-service inspection, testing, modifications, calibration, procurement, nonconformances and corrective action. Specifications and design change documents are reviewed by QA to assure appropriate design and quality requirements are included. The documents are reviewed in a depth sufficient to assure that applicable QA requirements (e.g., the necessary inspection requirements, final documented verification of implemented procedures and checklists, methods, and acceptance criteria) have been identified and specified therein. Evidence of the review is documented by concurrence or approval by the QA reviewer. Technical Specification changes are reviewed and approved by both the On-Site Review and Off-Site Review Groups prior to submittal to NRC for approval. After NRC approval the change is implemented at the station. All procedures and documents affecting safety are reviewed and approved and assured to be acceptable and implemented as required by the Technical Specification and the Corporate Quality Assurance Program. Quality Assurance performs the assuring responsibility as does the station management.

Question #45

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

Response:

Quality Assurance coverage is scheduled for activities requiring off-shift quality verification and, as stated in the response to NRC Question #7, additional QA personnel are assigned to Zion as required to cover the work activities during outages on an overtime basis or with staff from other sources within the Quality Assurance organization. Also note the response for NRC Question #9 for Quality Control involvement.

Item C Staff Position Enclosure 2

C. QA Staffing and Qualification Requirements

Paragraph 1

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.

Paragraph 2

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. Proficienty 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

Response to Item C Staff Position of Enclosure 2

Paragraph 1

The explanation as to the number of onsite/offsite QA/QC personnel is provided in the response to NRC Question #7. The basis for the Quality Assurance and Quality Control staff sizes is given in the response to NRC Question #8. The establishment of the level of qualifications and certifications for assigned tasks is explained in the response to NRC Questions #15 and #16

In addition Quality Assurance staffing levels are augmented during peak periods of maintenance, modifications, refueling and in-service inspection. The response to NRC Question #9 describes the provisions for Quality Assurance and Quality Control daily participation in meetings with the station staff involving discussions of daily and projected plant work loads and involvement with normal daily activities.

Paragraph 2

As for the education and training aspects to be considered relative to the qualification and certification program, the response to NRC Question #14 provides explanation and clarification of the indoctrination and training program; Question #15's response provides a system of acceptance criteria for qualification to meet the requirements of ANSI N45.2.6; and the response to NRC Question #16 describes the provisions which delineates the specific inspection; examination, test, or special process each certified person is qualified to perform. The CECo introduction and training and qualification program is 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 inspection, 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 for performing inspections, examinations and tests covered by item (b) above.

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

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.

Also, QA/QC personnel have been provided training so as to be familiar with or knowledgeable in the areas affecting quality appropriate to their assignments such as:

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

Question #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)

Response:

The Director of Quality Assurance (Operating) and the Quality Assurance Supervisors (Maintenance) meet the experience requirements of Section 4.4.5 of ANSI/ANS-3.1-1978.

Item B of Enclosure 2

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.

Response to Item B Staff Position of Enclosure 2:

The QA organization located on-site is responsible for the on-site QA activities and performs QA review, inspection, surveillance, and audit functions. This QA organization reports technically and administratively to off-site QA management but maintains close communication ties with the Plant Superintendent and the Station Staff. Personnel perform the independent inspection and verification functions. Quality Assurance personnel review and approve quality-related procedures and activities. The responses to NRC Question 5 as well as other responses provide additional information relative to this discussion.

Question #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.)

Response:

In reference to the table for Question 17's response, maintenance instructions and test procedures are required to have documented concurrence of CECo Quality Assurance. These instructions and test procedures are required as part of the second item, the Maintenance/Modification Procedures. Thus, in the process of review and approval of this procedure for every work package these two items are reviewed and approved by Quality Control and Quality Assurance.

Question #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.

Response:

Where a design or design change is authorized to be released for use prior to verification, a justification for this action is required to be documented and approved by responsible management and the unverified portion of the design output document (and all other design output documents and items based on the unverified data) is identified as such and controlled.

Question #49

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

Response:

The validity of the suppliers' certificate of conformance is verified by Quality Control and Quality Assurance at the time of receipt inspection and during source inspection, audits and inspections at the vendor facility. The criteria for validity of the suppliers' Certificate of Conformance requires a description of what the certification covers and the signature of the vendor's employee responsible for quality. The criteria used during audits and inspection are established from the design, specification and other procurement requirements on approved checklists.

Question #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)

Response:

Commonwealth Edison Company's Quality Assurance Program Topical Report, CE-1-A, has been revised to include in Revision 14 the later version of Regulatory Guides 1.28, Rev. 2; and 1.1.44 (1/79). For Regulatory Guide 1.26 and 1.29 refer to the response to NRC Question #1. The commitment and any exceptions to Regulatory Guide 1.29 will be included in the FSAR for Zion.

Question #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.

Response:

The responses to the series of NRC Quality Assurance Program Questions 1 through 51 and the Staff Positions involving

the Task Action Plan for Zion will be referenced in Commonwealth Edison Company Topical Report CE-1-A, Quality Assurance Program for Nuclear Ge erating Stations when concurrence with NRC on this Action Plan matter is established.