ENCLOSURE

Commonwealth Edison Company Docket No. 50-10, No. 50-237, No. 50-249, No. 50-295 and No. 50-304

Certain activities under your license identified below appear to be in violation of Regulatory requirements. These are considered to be of Category II severity:

 10 CFR 50, Appendix B, Criterion V states in Part: "Activities affecting quality shall be prescribed by documented . . . procedures, . . . appropriate to the circumstances and shall be accomplished in accordance with these . . ., procedures, . . ."

Contrary to the above:

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- a. A procedure (Q.P. No. 10-2) has been prepared for use in inspection at the fuel contractor. However, the procedure does not include requirements to 1) provide for the assignments of qualified inspectors; 11) prepare documented results of the inspections; 11) provide for management review of inspection results; iv) reinspect deficient areas; v) prepare inspection plans or check lists for each inspection or inspection type.
- b. Procedure Q.P. No. 10-2 requires that during the pre-manufacturing phase a schedule of audits will be established. However a schedule of audits of fuel contractors has not been prepared.
- c. Procedure Q.P. No. 10-2 requires that the Quality Arsuince Administrator verify completion of corrective action (taken by the fuel manufacturer on areas found deficient by the Nuclear Fuel Inspector).

However, no systematic method has been developed for following up on deficiencies and thereby, allow the Quality Assurance Administrator to verify completion of corrective actions.

2. 10 CFR 50, Appendix B, Criterion VII states in part: "Measures shall be established to assure that purchased material, . . . conform to the procurement documents. These measures shall include evidence of quality furnished by the contractor, inspection at the contractor source, and examination of products upon delivery. The effectiveness of the control of quality by contractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity

of the produce or services." Also Criterion IV requires that contractors provide a quality assurance program consistent with the Appendix B criteria.

Contrary to the above, inspections of fuel contractors were incomplete in that these inspections were not conducted against each of the Appendix B Criteria. For example:

- a. Criterion I Organization. Inspections of fuel contractors do not include a determination that the fuel contractors organization provides that: 1) the authority and duties of persons performing quality assurance function are clearly established and delineated in writing; and 11) such persons have sufficient authority, organizational freedom and independence to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.
- b. Criterion III Design Control. Although the responsibility for fuel design and design review is delegated to the nuclear fuel contractor. the inspections did not determine the establishment or effectiveness of the design control measures applied by the fuel contractor.
- c. Criterion IV and VII Control of Procurement Documents and Purchased Material. Inspections of fuel contractors did not include a determination that the fuel contractor is assuring that adequate requirements are included in his procurement documents. These inspections did not include a determination that material purchased by the fuel contractor conforms to the procurement documents.
- d. Criterion IX Control of Special Processes. Inspections of fuel contractors did not include a determination that the special processes used in the manufacture of nuclear fuel are accomplished by qualified personnel using qualified procedures.
- e. Criterion XVI Corrective Action. Inspections of the fuel contractors did not include a finding that i) the fuel contractor determines the causes of conditions adverse to
- 1/ "Responses to AEC Inquiry Concerning Commonwealth Edison's Quality Assurance Program for Nuclear Fuel," dated March 22, 1973, submitted to Licensing on May 16, 1973.

quality; ii) takes corrective action to preclude repetition; iii) documents causes and corrective actions; and iv) reports these to appropriate levels of his management.

3. 10 CFR 50, Appendix B, Criterion XVI states in part: "Measures shall be established to assure that conditions adverse to quality, such as deficiencies, deviations, defective material, and nonconformances are promptly identified and corrected. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Contrary to the above, a) identification of significant conditions adverse to quality from the fuel inspector's inspections were not reported to appropriate levels of management and b) corrective actions were not documented and reported to appropriate levels of management.

4. 10 CFR 50, Appendix B, Criterion XVIII states: "A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, shall be taken where indicated."

Contrary to the above, no internal audits had been performed to verify compliance with, nor determine the effectiveness of the quality assurance program for the purchase of nuclear fuel.