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

SEP 15 1980

Docket No. 50-320

Mr. R. C. Arnold
Senior Vice President
Metropolitan Edison Company
Middletown, PA 17057

Dear Mr. Arnold:

Commission regulations (10 CFR 50.59) specify actions which must be taken by the licensee if a licensee proposes to make changes in a facility or procedures which are described in the Safety Analysis Report.

As you have been previously advised, and consistent with the Commission's November 21, 1979 Statement of Policy and Notice of Intent to Prepare a Programmatic Environmental Impact Statement, unless it is otherwise determined to be in the best interest of the public health and safety, we will not approve any method for decontamination of the contaminated water in the TMI-2 reactor building sump prior to completion of our environmental review in the Programmatic Environmental Impact Statement. The NRC staff considers that your proposed method to decontaminate the reactor building sump water, the Submerged Demineralizer System (SDS), would be a facility change as described in 10 CFR 50.59 which may require prior NRC approval. Accordingly, part of our review of the SDS will require submission by Met Ed of a comprehensive written safety evaluation to determine if such a change would involve an unreviewed safety question and/or a change in the Technical Specifications for the facility, and hence a license amendment.

For your information the attached, a recently issued Office of Inspection and Enforcement Information Circular, serves to highlight the NRC staff's position on this subject.

In order to coordinate our review effectively we request to be informed within two weeks when your safety evaluation for the SDS will be submitted.

Sincerely,

Bernard J. Snyder

Bernard J. Snyder, Program Director
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Office of Nuclear Reactor Regulation

Enclosure: IE Circular No. 80-18

cc: See attached

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

DUPLICATE

August 22, 1980

IE Circular No. 80-18: 10 CFR 50.59 SAFETY EVALUATIONS FOR CHANGES TO RADIOACTIVE WASTE TREATMENT SYSTEMS

Discription of Circumstances:

Recent inspection efforts at operating power reactors have revealed numerous instances in which licensees have failed to perform adequate safety evaluations to support changes made to the design and/or operation of facility radioactive waste treatment systems. These safety evaluations are required by the regulations of 10 CFR 50.59 whenever changes are made in the facility as described in the Safety Analysis Report (SAR).

The inadequacies of the evaluations have caused radiological safety hazards to occur unidentified and therefore to remain unevaluated and uncorrected. In two particular cases, the inadequately evaluated system changes resulted in system failures that caused an uncontrolled release of radioactivity to the environment. In each of these situations, a proper 10 CFR 50.59 safety evaluation should have identified and corrected deficiencies in the system modification and/or operation and would have prevented the inadvertent release of radioactivity.

NRC followup examination of the situation indicates that the inconsistency and/or inadequacy of licensee safety evaluations may be widespread. A wide range of opinions seems to exist among licensees as to what constitutes an appropriate 10 CFR 50.59 safety evaluation, particularly for radwaste systems. Therefore, the following discussion and/or guidance is provided for licensee use in preparing future 10 CFR 50.59 safety evaluations to support changes in the design and/or operation of the radioactive waste treatment systems of licensed facilities.

Although the contents of this guidance are specifically directed to the radioactive waste systems, the general principles and philosophy of the 10 CFR 50.59 safety evaluation guidance are also applicable to the facility design and operation as a whole; thus, the application of 10 CFR 50.59 should reflect a consistent approach.

Discussion:

The requirements of 10 CFR 50.59 are composed of three essential parts. First, paragraph (a)(1) is permissive in that it allows the licensee to make changes to the facility and its operation as described in the Safety Analysis Report without prior approval, provided that a change in Technical Specifications is not involved or an "unreviewed safety question" does not exist. Criteria for determining whether an "unreviewed safety question" exists are defined in paragraph (a)(2). Second, paragraph (b) requires that records of changes made under the authority of paragraph (a)(1) be maintained. These records are required to include a written safety evaluation that provides the

basis for determining whether an "unreviewed safety question" exists. Paragraph (b) also requires a report (at least annually) of such changes to the NRC. Third, paragraph (c) requires that proposed changes in Technical Specifications be submitted to the NRC as an application for license amendment. Likewise, proposed changes to the facility or procedures and the proposed conduct of tests that involve an "unreviewed safety question" are required to be submitted to the NRC as an application for license amendment.

Any proposed change to a system or procedures described in the SAR, either by text or drawings, should be reviewed by the licensee to determine whether it involves an "unreviewed safety question." Maintenance activities that do not result in a change to a system (permanent or temporary), or that replace components with replacement parts procured with the same (or equivalent) purchase specification, do not require a written safety evaluation to meet 10 CFR 50.59 requirements. However, a safety evaluation is required to meet the provisions of 10 CFR 50.59 and any change must be reported to the NRC as required by 10 CFR 50.59(b) if the following circumstances occur: (1) components described in the SAR are removed; (2) component functions are altered; (3) substitute components are utilized; or (4) changes remain following completion of a maintenance activity.

Notice to Licensees:

For all cases requiring a written safety evaluation, the safety evaluation must set forth the bases and criteria used to determine that the proposed change does or does not involve an "unreviewed safety question." A simple statement of conclusion in itself is not sufficient. However, depending upon the significance of the change, the safety evaluation may be brief. The scope of the evaluation must be commensurate with the potential safety significance of the proposed change or test. The depth of the evaluation must be sufficient to determine whether or not an "unreviewed safety question" is involved. These evaluations and analyses should be reviewed and approved by an appropriate level of management before the proposed change is made.

An important part of the "unreviewed safety question" determination is the evaluation and analysis of the proposed change by the licensee to assure that (1) potential safety hazards are identified, and (2) corrective actions are taken to eliminate, mitigate, or control the hazards to an acceptable level. All realistic failure modes and/or malfunctions must be considered and protection provided commensurate with the potential consequences. All applicable regulatory requirements, including Technical Specifications, must be complied with so that the proposed change shall not represent an "unreviewed safety question." Also, the margin of safety as defined in the bases of the Technical Specifications shall not be reduced by the proposed change.

For radioactive waste systems, the appropriate portions of 10 CFR 20, 30, 50, 71, and 100, the facility Technical Specifications, and 40 CFR 190 (Environmental Dose Standard) are applicable.

Additional specific criteria that should be reviewed prior to the modification of radioactive waste systems are presented below:

(1) System modifications should be evaluated against the seismic, quality group and quality assurance criteria in Regulatory Guide 1.143. Design

provisions for controlling releases of radioactive liquids, as presented in Regulatory Guide 1.143, should also be evaluated.

(2) Radiological controls should be evaluated against the criteria in Regulatory Guide 1.21 and Standard Review Plan Section 11.5, "Process and Effluent Radiological Monitoring and Sampling Systems."

(3) Systems involving potentially explosive mixtures should be evaluated against the criteria in Standard Review Plan Section 11.3, "Gaseous Waste Management System," subsection II, item 6.

(4) System design and operation should be evaluated to assure that the radiological consequences of unexpected and uncontrolled releases of radioactivity that is stored or transferred in a waste system are a small fraction of the 10 CFR 100 guidelines; i.e., less than 0.5 rem whole body dose, 1.5 rem thyroid from gaseous releases, and less than the radionuclide concentrations of 10 CFR 20, Appendix B, Table II, Column 2 from liquid releases at the nearest water supplies. (See Standard Review Plan Sections 15.7.1, 15.7.2, and 15.7.3 for more details.)

The evaluation must include an analysis encompassing the above criteria to the extent that the criteria are applicable to the proposed changes; i.e., if the modifications involve a change addressed by the above regulations and criteria, then the modifications must be evaluated in terms of these regulations and criteria.

In conclusion, for any change in a facility radioactive waste system as described in the SAR, a safety evaluation is required in accordance with 10 CFR 50.59. In this safety evaluation and the "unreviewed safety question" determination, the evaluation criteria in Items 1-4 above should be used. If the proposed modification (design, operation, or test) represents a departure from this evaluation criteria, one of the following actions should be taken:

(1) The proposal should be modified to meet the intent of the criteria;

(2) The evaluation/determination must present sufficient analyses to demonstrate the acceptability of the departure; or,

(3) Commission approval must be received prior to implementing the modification (i.e., an unreviewed safety issue may be involved).

No written response to this circular is required. If additional information regarding this subject is required, contact the Director of this office.