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Ref. # 10CFR50.109

July 11, 1997

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U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

SUBJECT: REPLY TO NOTICE OF VIOLATION AND REQUEST FOR BACKFIT ANALYSIS

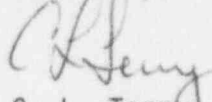
RE: NRC Inspection Report 50-445/97-12; 50-446/97-12 and Notice of Violation

Gentlemen:

The referenced Inspection Report identified four violations. The attachment to this letter provides the response to the violation associated with failure to perform safety evaluations for configuration changes that involved changes to drawings in the Final Safety Analysis Report. The response to the remaining violations is provided in TXX-97143, dated July 11, 1997.

Because this response raises a number of backfitting issues, we are providing copies to the Regional Administrator and the Executive Director of Operations in accordance with Manual Chapter 0514.

Sincerely,

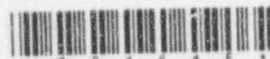

C. L. Terry

BSD:bsd
Attachment

c - L. J. Callan, Executive Director for Operations (EDO)
E. W. Merschoff, Region IV
J. I. Tapia, Region IV
T. J. Polich, NRR
Resident Inspectors, CPSES

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VIOLATION

- C. 10 CFR 50.59(a)(1) states, "...the holder of a license authorizing operation of a production utilization facility may (i) make changes in the facility as described in the safety analysis report...unless the proposed change...involves...an unreviewed safety question."

10 CFR 50.59(b)(1) states, "...the licensee shall maintain records of changes in the facility...to the extent that these changes constitute changes in the facility as described in the safety analysis report...These records must include a written safety evaluation which provides the basis for the determination that the change...does not involve an unreviewed safety question."

Contrary to the above, the licensee implemented the following design change notices, each of which involved a change to the drawings contained in the safety analysis report, without performing a written evaluation providing the basis for concluding that the change did not involve an unreviewed safety question.

- DCN 10490, which changed the position of three valves in the post-accident sampling system.
- DCN 10445, which removed the internals from check valves in the instrument air system.
- DCN 9013, which generically replaced ball valves with globe valves.
- DCN 10174, which removed two valves from the feedwater system.

This is a Severity Level IV violation (Supplement I)(50-445;-446/9712-05).

REPLY TO VIOLATION

In citing the above as a violation, TU Electric believes the NRC has modified its position on a previously accepted TU Electric procedure. Therefore, the position reflected in the violation constitutes a backfit as defined in 10 CFR 50.109.

10 CFR 50.109(a)(1) states, in part, "Backfitting is defined as the modification of ...procedures...required to design, construct or operate a facility...which may result from ... the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position..." This was clarified in the Statement of Considerations to the backfit rule when it was promulgated (see 50 FR 38101) which states, in part, "...the Commission opts to adopt a management process not only for the promulgation of regulations as backfit instruments, but also for the lower tier staff review and inspection processes known to result in reactor plant changes....[T]his definition includes both cause and effect of backfitting. It may also be noted that

'cause' includes not only Commission rules and orders, but staff interpretations of those rules and orders. This is not to say that staff interpretations of rules are viewed by the Commission as being legal requirements. Clearly, they are not. Nevertheless, staff interpretations of broadly stated rules are often necessary to give a rule effect and in some instances may be a causal factor in initiating a backfit."

During the Backfitting Workshops conducted in 1986, one of the questions addressed was whether it would constitute a backfit if the NRC were to conduct an inspection and determine that a licensee needs to change a previously agreed-upon procedure. The NRC staff responded that when the NRC has previously approved the procedure, the licensee has a rightful expectation that the procedure will continue to satisfy the NRC. The NRC must conduct a backfit analysis before it can require the licensee to change this agreed-upon procedure. This position is further reiterated in NUREG-1409 (Section 3.3 Question (1)) which states in part:

- (1) *If an inspector has previously accepted (i.e., provided tacit approval of) a licensee's method, does a specific request for change constitute a backfit and if so, is a backfit analysis required?*

A new or revised staff position affecting the design of systems, structures, and components or the procedures or organization required to design and construct or operate a facility after issuance of the operating license is a backfit. Whether a backfit analysis is required depends on the basis for the backfit. A backfit analysis is required when the backfit would result in a cost justified substantial safety enhancement. If the determination is made that the action is needed to provide an adequate level of protection or required to bring a facility into compliance, then no backfit analysis is required.....

Cases where an inspector provides tacit approval are relatively rare.....For the purpose of this question, it would most likely arise in connection with review of a licensee response to an inspection report.

Explicit approval could be provided in an inspection report that states that a particular approach is acceptable.....

10 CFR 50.109(a)(2) states, in part, "...the Commission shall require a systematic and documented analysis pursuant to paragraph (c) of this section for backfits which it seeks to impose."

10 CFR 50.109(a)(4) states, in part, "The provisions of ... this section are inapplicable...where the Commission or staff...finds and declares...[t]hat a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission or into conformance with written commitments by the licensee...." This exception was explained by the Commission when the rule was issued as stated in 50 FR 38103, "The compliance exception is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified

interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard." 10 CFR 50.109(a)(6) explains the analysis and documentation necessary to make a finding and declaration as per (a)(4).

In "NRC Inspection Report 50-445/97-12; 50-446/97-12 and Notice of Violation" the NRC staff states (section E2.4, page 20), in part,

The inspectors reviewed ... "10 CFR 50.59 Review Guide," Revision 4.... The inspectors noted that the review guide defined "trivial changes" as being modifications that did not constitute changes to the facility as described in the Safety Analysis Report. The review guide stated that trivial changes did not require a 10 CFR 50.59 safety evaluation and instructed licensee personnel to answer "NO" to the relevant 10 CFR 50.59 screening questions. Within the review guide, the licensee defined seven categories of "trivial changes" as follows....

- Deletion of existing information which was believed to be below the level of detail required to be included in the Final Safety Analysis Report*
- Minor changes, which had no potential safety impact*

The inspectors consulted with the Office of Nuclear Reactor Regulation and concluded that the last two categories of the licensee's definition allowed changes [that] were potentially beyond the scope of trivial changes as discussed in NRC guidance documents.

With regard to deletion of detail, 10CFR50.59 addresses changes to the facility, procedures and tests "as described in the FSAR." Removal of detail from the FSAR which is not the result of changes to the plant, or is not a correction to bring the FSAR into agreement with the physical plant, does not specifically fall under the requirements of 10CFR50.59. The level of detail to be included in the FSAR is contained in regulatory requirements and guidance such as 10CFR50.71(e), RG 1.70, NUREG-0800, license conditions, licensee commitments and other regulatory guidance documents. Consistent with these documents, removal of excessive detail can be performed without written evaluation and thus the screening criterion described above is appropriate.

The inspection report also stated that the use of the "trivial" screening criterion (i.e., no potential for safety impact) was unacceptable in part because it lacked a regulatory basis. The inspection report states:

The NRC definition of "trivial changes" [discussed, in part, in Inspection and Enforcement Manual Chapter, Part 9800, "CFR Discussions, Changes to Facilities, Procedures and Tests (or Experiments)," Section D.7.d, dated January 1, 1984] included editorial, organizational, and typographical changes, but did not extend to changes involving physical changes to the plant configuration that resulted in a revision to plant drawings included in the Final Safety Analysis Report.

TU Electric believes its approach is consistent with existing NRC guidance. Inspection and Enforcement Manual Chapter, Part 9800, Section D.7.d, dated January 1, 1984, in fact states (emphasis added):

General Guidance. It should be noted that the SARs for a number of older facilities contain floor plans of onsite buildings that may include trivial detail such as the locating of dividing walls between various offices. From a rigid reading 10 CFR 50.59, it is possible to infer that the removal of a dividing wall between two offices constitutes a change from the facility described in the SAR, and therefore requires a safety evaluation. However, the intent of 10 CFR 50.59 is to limit the requirements for written safety evaluations to facility changes, tests, and experiments which could impact the safety of operations.

Thus, contrary to the inspection report conclusion, the Inspection and Enforcement Manual Chapter, Part 9800, Section D.7.d, dated January 1, 1984, does provide regulatory support for the TU Electric "trivial" change screening criterion. The above paragraph clearly indicates that the NRC Inspection and Enforcement Manual recognizes a level of detail regarding changes to plant configuration as described in the FSAR that does not require a written safety evaluation. Administrative procedure, STA-707, "10 CFR 50.59 Reviews" and the "10 CFR 50.59 Review Guide," were developed with specific criteria to determine when changes to the plant do not require written evaluations. The meaning and application of the "trivial" criterion is demonstrated in the examples cited in the subject NOV. In these four examples, there was clearly no potential impact on safety and further no written descriptive details in the FSAR were involved as they only affected minor non-safety consequence details on FSAR figures as described below:

DCN 10490 changed the normal position of three CCW valves shown in the FSAR figure for the post-accident sampling system (PASS). The valve position changes were performed to bypass and isolate a leaky non-safety related PASS sample cooler flow transmitter. Existing procedures provide an alternate method for verifying sufficient CCW flow to the sample cooler. The change did not affect the ability to perform post accident sampling. Revising the FSAR figure to show different normal valve positions clearly had no potential for safety impact.

DCN 10445 removed the internals from a check valve in the instrument air system to remove the potential for failure of the check valve due to check valve slam when the compressor cycled. The change had no potential for safety impact because the function of the valve was performed by an internal check valve which was part of the design of the new replacement air compressor.

DCN 9013 generically replaced globe valves and hermetically sealed valves in non-process applications with ball valves. A technical evaluation was performed to establish functional equivalency for each application. The change had no potential for safety impact because all functional requirements of the globe valves and hermetically sealed valves are met by the replacement ball valves.

DCN 10174 removed two drain valves from the feedwater system due to leakage and replaced them with welded caps. The valves were originally installed to drain the system during maintenance. The change had no potential for safety impact because these valves are normally not used and the system is normally drained via the Chemical Feed system.

The above cited examples demonstrate that the TU Electric procedure and guidance documents appropriately screen out minor plant changes that could not potentially impact plant safety. This approach satisfies the intent of 10 CFR 50.59 as described in the Inspection and Enforcement Manual Chapter, Part 9800, Section D.7.d, dated January 1, 1984, "to limit the requirements for written safety evaluations to facility changes, tests, and experiments which could impact the safety of operations."

The procedure and guidance have been reviewed by the NRC staff on multiple occasions, most notably during operational readiness reviews and 10 CFR 50.59 audits. The inspections not only reviewed the procedures but also examined specific applications. In none of these inspections were the screening criteria above found deficient and, in several cases, applications which applied these criteria were specifically found to be acceptable.

In "NRC Inspection Report 50-445/97-12; 50-446/97-12 and Notice of Violation" the NRC staff states that, contrary to TU Electric's assertion, the use of the "trivial" screening criteria had not been previously reviewed and approved. Specifically, the comments provided by the NRC in Inspection Report 50-445; -446/93-32 did not constitute approval.

TU Electric disagrees. The "trivial change" criteria, contained in the CPSES 10 CFR 50.59 Review Guide, were reviewed by the NRC as part of the 10 CFR 50.59 inspection. The inspection report states in part:

The licensee had examined NSAC 125 guidance and had prepared a 10 CFR 50.59 "review guide" for preparers to use in writing safety evaluations.... This programmatic assistance was considered by the inspectors to be a positive characteristic of the program.

With regard to approval of the "trivial" criterion (i.e., no potential for safety impact) the subject inspection report states with respect to a specific change being evaluated by the inspector that:

Implementation of the change was clearly a change to the facility as described in licensing basis documents. This temporary modification should have been identified as a "trivial" type change. That is, a change having "no potential safety impact (e.g., affecting safe shutdown or the safety of operations)." This change had little safety significance, since the probe was designed to be used with several inoperable sensors.

The above NRC inspection report comment was written as a result of the review of 14 screens which involved modifications to plant configuration. Several involved changes to the plant as described in the FSAR and used the "trivial" change criterion (i.e., no potential for safety impact) as the basis for not performing a written evaluation. The inspectors found all the screens that used the "trivial" criterion to be acceptable. The inspectors

challenged one of the screens that did not use the "trivial" criterion. The inspector recommended that the "trivial" change criterion be applied as the basis for not providing a written evaluation. In TU Electric's view, this action represented explicit approval of the criterion.

The Summary for the inspection report concluded:

In general, 10 CFR 50.59 screenings and evaluations were satisfactorily performed. A good program has been established with good engineering support of the activities.

In "NRC Inspection Report 50-445/97-12; 50-446/97-12 and Notice of Violation" the NRC staff stated that the use of two of the "trivial" screening criteria was unacceptable in part because they were not previously reviewed by the Office of Nuclear Reactor Regulation (NRR).

....Nevertheless, these views and concerns cannot be reasonably construed to be NRC approval of the licensee's program for use of "trivial changes". The example represented an isolated instance, which was not reviewed by the Office of Nuclear Reactor Regulation. Therefore, the inspectors concluded that this current violation is appropriate.

The NRC conducted an extensive audit of TU Electric's 10CFR50.59 program and documented its findings in Inspection Report 50-445;-446/93-32. The NRC inspection team for that inspection consisted of members of Nuclear Reactor Regulation (NRR) and members of Region IV. In fact 3 of the 4 inspection team members were from NRR including the Unit 1 and Unit 2 NRC Project Managers. Had TU Electric sought a specific NRR review of the "trivial" criteria, the project managers would have been the specific individuals who would have provided the NRR position. Notwithstanding the above, there is nothing in the regulations or NRC guidance that suggests that NRC approval can only be obtained through NRR. On the contrary, as specifically stated in the previously referenced example from NUREG-1409, NRC-required revisions to procedures previously approved by an inspection report, explicitly or tacitly, may constitute backfits.

Based on the above, TU Electric concludes that the position in Inspection Report 50-445/97-12; 50-446/97-12 as quoted above, which finds two screening criteria for trivial changes unacceptable and which served as the basis for the subject potential violation, is a plant-specific backfit within 10 CFR 50.109; therefore, in accordance with 10 CFR 50.109, the NRC staff should perform the required backfit analysis (per the subject regulation and applicable guidance documentation such as NUREG-1409, "Backfitting guidelines" dated July 1990; NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook" draft report dated August 1993; and the NRCs Staff Manual Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants" dated February 1986). Per this regulation and related guidance and supplementary material, TU Electric understands that further action in this matter will be held in abeyance until the backfit analysis is completed but that all other licensing action for Comanche Peak Steam Electric Station (CPSES) will continue, unaffected by this request. Per NUREG-1409, "Backfitting guidelines" dated July 1990, "Licensees shall not be penalized by the staff for raising backfit questions

or filing backfit appeals. As stated in NRC Manual Chapter 0514, if immediate imposition is not necessary, staff proposed backfits should not be imposed and plant construction, licensing action, or operation should not be delayed during an appeal."

TU Electric requests that the NRC staff also consider the impact of this backfit request while performing the backfit analysis. TU Electric has been applying these criteria, with the knowledge of the NRC staff, since CPSES Unit 1 was licensed in 1990 and since Unit 2 was licensed in 1993. Almost all screens (hundreds) may need to be reviewed and, if these criteria were applied, 10 CFR 50.59 evaluations performed. TU Electric believes that not a single screen will result in an unreviewed safety question (USQ), since none had the potential to affect safety. There will be no safety benefit and TU Electric resources will be drawn away from potentially more safety significant matters. TU Electric also recently replaced many of the FSAR figures with plant drawings. This was done for several reasons including the fact that the NRC and all other users would be provided with more detailed information on CPSES. This change was based on the availability of the "trivial change" concept and the two criteria of concern. Without these criteria, the update of these drawings would be too resource intensive without a commensurate benefit to safety. TU Electric may be forced to return to more simplified FSAR drawings (which will still require more resources to develop and maintain without the "trivial" criteria of concern).

TU Electric realizes that this backfit issue overlaps significantly with several policy issues being reviewed by the Commission and the NRC staff (including SECY-97-035 and SECY-97-036). As a result, it may be premature to perform these backfit analyses until these broader issues are resolved and the overall policy and NRC positions are clarified and established in the proper manner. If the NRC feels that the best course of action is to defer action on these backfits until the broader issues are resolved, TU Electric will concur.

TU Electric also understands (see NRC Staff Manual Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants" dated February 1986) that it may appeal a backfit analysis and an NRC determination that a issue is not a backfit. TU Electric is taking no action along those lines at this time but reserves the right to make such appeals following the NRC's resolution of the request in this letter.

In summary, TU Electric continues to believe that its present 10 CFR 50.59 implementation program, including the "trivial" change screening criteria, complies with 10 CFR 50.59 and was approved by the NRC during its inspection process. The new position proposed by Inspection Report 50-445; 50-446/97-12 is a plant specific backfit which must be processed per 10 CFR 50.109.