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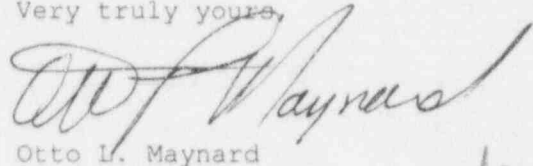
Reference: Federal Register Notice, 62 FR 24997, dated May 7, 1997
Subject: Docket No. 50-482: Comments on NUREG-1606, "Proposed
Regulatory Guidance Related to Implementation of 10 CFR
50.59 (Changes, Tests, or Experiments)"

Gentlemen:

As noted in the referenced Federal Register Notice, the NRC published its proposed guidance for the implementation of 10 CFR 50.59 as NUREG-1606 and solicited comments from the public. This letter offers Wolf Creek Nuclear Operating Corporation's (WCNOC's) comments on NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Test, or Experiments). WCNOC supports the comments made by the Nuclear Energy Institute (NEI) in their letter dated July 7, 1997. Additional comments are offered in the attachment to this letter. In general, WCNOC believes that in issuing NUREG-1606, major progress was made toward unifying both the industry and NRC perspectives on 10 CFR 50.59.

If you have any questions concerning this response, please contact me at (316) 364-8831, extension 4000, or Mr. Richard D. Flannigan at extension 4500.

Very truly yours,



Otto L. Maynard

OLM/jad

Attachment

cc: W. D. Johnson (NRC), w/a
E. W. Merschoff (NRC), w/a
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**Wolf Creek Nuclear Operating Corporation (WCNOC) Comments on NJREG-1606,
"Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests,
or Experiments)"**

Section	Comment
General Comment 1	<p>The term "licensing basis" is used extensively in this guidance document, but is not defined and appears to be used and interpreted in a wide variety of ways.</p> <p>It is especially important not to use the phrase "licensing basis" in guidance since, as stated in Section IV.A, one of the policy issues being considered is revision of the rule to better define what is included in the licensing basis. Also as stated in Section I, Introduction, when discussing Millstone issues, "The lessons-learned task group concluded that (1) the concepts of current licensing basis and design bases are not clearly understood by some licensees and NRC staff; (2) both licensees and staff have difficulty identifying and locating bases documents; and (3) bases documents are not always appropriately used in NRC licensing and inspection activities and in licensee design and facility changes."</p> <p>If it means that information that was considered by the NRC during the operating license review and updated to the current facility and procedures, then the phrase appears to be the same as the definition of SAR (see III.F.4, first sentence).</p>
General Comment 2	<p>The term "design basis" is used throughout this guidance document, but the context of use appears to be different in some cases. (The terms "Design Basis" or "Design Bases" are used in the following sections: I, 4th, 7th, 8th ¶; III.B.4,, last ¶; III.C.4, 2nd ¶; III.E.4, 2nd ¶; III.F.4, 1st ¶; III.H.4, 1st, 2nd ¶; III.L.4, title; III.L.4 ¶; III.M.4, 2nd ¶; III.O.4, 2nd, 8th, 10th, 11th ¶; III.Q, title; III.Q.3, 3rd, 4th, 5th, 6th ¶; III.Q.4, 1st, 3rd, 4th ¶; III.S.4, 1st, 2nd, 5th ¶; III.T.2, 1st ¶; III.V.3, 1st ¶; III.V.4, 2nd ¶; IV.A.3, 1st, 2nd, 3rd ¶)</p> <p>Most uses of the term "design basis" appear to be consistent with the 10 CFR 50.2 definition as it relates to design information satisfying the plant's Principle Design Criteria or General Design Criteria (i.e., those specific functions or related values chosen for design purposes to implement and satisfy the applicable General Design Criteria). The accidents and events that are analyzed to ensure that the plant can satisfy the GDCs are the "design basis" accidents and events. This way of defining design basis appears to be consistent with the following sections:</p> <p style="padding-left: 40px;">Section III.H.4 discusses "design basis" in terms of accidents and events - "those anticipated transients and design basis accidents evaluated in the SAR (so-called Chapter 15 events), as well as events described in the SAR which the plant is designed to endure, such as earthquakes, fire, flood, high winds, tornadoes, missiles, offsite hazards and high energy line breaks. This should also include events or conditions added to the design and licensing basis through regulations and orders such as anticipated transient without scram and station blackout."</p> <p style="padding-left: 40px;">Section III.L.4 discusses "design basis" in terms of reportability - "The circumstances should also be reviewed for reportability under 10 CFR 50.72 and 10 CFR 50.73 with respect to operation outside the design basis."</p> <p style="padding-left: 40px;">Section III.Q.4 discusses "design basis" in terms of accidents and events - "Further, certain accidents may have been considered sufficiently unlikely that protection from their effects was not required ("outside the design basis"). In these instances, a design basis has been established for the facility which thus defines the "accidents previously evaluated."</p> <p>WCNOC recommends that the uses of the term "design basis" in the above sections remain as-is.</p>

Section	Comment
General Comment 2 (con't)	<p>Other instances of use of the term "design basis" appear to conflict with the above definition.</p> <p>Section III.F.4, appears to conclude that "the information in the FSARs that presents the purpose, quality, kind, number, condition, function, operation, use, design, or material of systems, structures or components" are considered part of the design basis, and even suggests that this type of information is included in the definition of 10 CFR 50.2.</p> <p>Section IV.A, part A.3 appears to be referring to information on the functional design. - "As discussed in the sections on SAR and on deleting information from the SAR, all of the design bases or other information that the staff would want to have subject to evaluation may not be contained in existing plant SARs." By virtue of the requirement in 10 CFR 50.34(b) that the "final safety analysis report shall include information that describes the facility, presents the design bases...", and the NRC issuance of each operating license based on that information, all of the design bases ARE contained in each plant's SAR.</p> <p>The usage of "design basis" in both of these examples does not appear to be consistent with the 50.2 definition and goes well beyond the context of the term as used in other sections of the guidance. WCNOG recommends changing the phrase "the design basis" in section III.E.4 and section IV.A.3 to "the information related to design".</p> <p>WCNOG also recommends deleting the reference to 10 CFR 50.2 in Section III.E.4. The portion of FSAR information that meets 50.2 definition appears to be only a portion of what is described in section III.E.4. Since there is a great deal of debate regarding what is meant by 50.2, guidance on 50.59 should not attempt to resolve this issue. WCNOG recommends changing the last sentence to: "The above type of information for systems, structures and components that are included in the FSAR is subject to evaluation within 10 CFR 50.59."</p>
III.A, B, C, &E general comment	<p>There seems to be a great industry effort to define in detail whether the activity being performed is or is not a change, does or does not exactly match the definition of facility or procedures, or is or is not described in the USAR. The reason for this great effort appears to be to manage the number of activities subjected to the screening portion of the regulation. However, excluding activities from a screening activity appears to be contrary to the intent of the NUREG guidance.</p> <p>WCNOG believes it is very important that the industry and the NRC resolve this difference and develop a very succinct set of "bottom line" statements that encompasses the intent of this portion of the regulation.</p>

Section	Comment
III.A, B, C, & E general comment (con't)	<p>However, activities should be considered for exemption from this evaluation if it can be clearly shown that activity:</p> <p>is allowed by regulation (e. g., Tech Spec allowed outage time or 10CFR50, App. B, Crit. XVI for implementing corrective action at the next available opportunity), or</p> <p>that the activity was not considered by, or would not have affected the decision of, the NRC when they conducted their safety review for the operating license (e. g., Severe Accident Management activities or activities related to beyond design basis events).</p> <p>Documentation of exemption from evaluation should be available for review.</p> <p>This definition includes the guidance included in Section III.0.4 and the second paragraph of Section III.4.C.</p>
III.A.4, Middle paragraph	<p>In (c), the term "part of the licensing basis" is not defined and appears to be interpreted in a wide variety of ways. If it means that information that was considered by the NRC during the operating license review and updated to the current facility and procedures, then the phrase appears to be the same as the definition of SAR (see III.F.4, first sentence).</p>
III.A.4, Middle paragraph	<p>In (b), as stated, the long list of potential affects certainly need to be considered in a change process, but only need to be considered under 50.59 if the change impacts descriptions in the SAR. For the most part, the impact of the proposed change on this list of items is required by Appendix B to be determined when assessing the safety of the proposed change. As stated in section II, determining the safety of a proposed change is not the same as determining , under 50.59, whether a change must be submitted to the NRC prior to implementation. To be consistent with the other items in this paragraph, suggest changing the first part of (b) to: "whether the activity would affect SAR descriptions of redundancy, diversity,..."</p> <p>This change would also make this paragraph consistent with the screening guidance of III.G.</p>
III.B, III.C	<p>The definitions of "facility" and "procedures" should be the phrases "facility as described in the SAR" and "procedures as described in the SAR". The portions of the NRC position on III.B.4 and III.C.4 that describe what is covered under 50.59 relate only to those descriptions of the facility or procedures that are contained in the SAR.</p>
III.B.4	<p>Modify the last sentence to clarify exactly what the phrase "that are described in the SAR" applies to. The phrase should apply to "information" rather than "SSCs". As written, it could be interpreted that design requirements and safety analysis information which is not described in the SAR (but is associated to those SSCs that are described in the SAR) should be covered under 10 CFR 50.59. This does not appear to be consistent with the definition of "change" in III.A.4.</p>

Section	Comment
III.D.4	<p>The following sentence is not consistent with 10 CFR 50.2:</p> <p>"The above type of information for systems, structures and components that are included in the FSAR are considered part of the design basis, and subject to evaluation, that is, they are within 10 CFR 50.2 and 50.59."</p> <p>The portion of FSAR information that meets 50.2 definition is only a portion of what is described in the paragraphs above. There is a great deal of debate regarding what is meant by 50.2. Guidance on 50.59 should not attempt to resolve this issue. The statement should be:</p> <p>"The above type of information for systems, structures and components that are included in the FSAR is subject to evaluation within 10 CFR 50.59."</p>
III.G	<p>This section does not define the purpose of Screening. A guidance document on 50.59 should define this term. Suggest: "The purpose of "screening" is to determine the need to perform an evaluation as to whether a change must be submitted to the NRC prior to implementation (50.59 evaluation)"</p>
III.G.4	<p>The terms "such activities", "records", "changes already made", and "other reference documents" could easily be interpreted to apply to analyses of the proposed change for the impact on safety. Section II emphasizes the importance of separating the analysis for safety from the 50.59 evaluation (i. e., determination whether the proposed change requires prior NRC approval).</p> <p>If this sentence is intended to refer to the analysis for safety, recommend deleting it. Including extensive guidance of this type implies that the analysis for safety is part of the 50.59 regulation, when it clearly is not, as explained in Section II.</p> <p>If it is intended that this sentence refer to a screening, suggest making the following changes:</p> <p>Change "performing such activities" to "performing screenings" to remove potential ambiguity as to what "activities" means.</p> <p>Change "accessible records of the SAR" to "access to the SAR". The term "records" implies documents controlled per 10 CFR 50, App. B.</p> <p>Change "changes already made that have not been included in the SAR" to "SAR changes that have not yet been included in the SAR". As written, it may be misinterpreted to imply that all changes are included in the SAR.</p> <p>Change "other reference documents" to "other documents incorporated by reference in the SAR". Section III.F.4 states "The rule requires all information described in the SAR be evaluated to see if the change would make the information in the SAR no longer true or accurate" Also as stated in III.F.4, "the SAR includes documents that are referenced as part of the description, but not documents merely listed as references".</p>

Section	Comment
<p>III.G.4, last paragraph</p>	<p>The term, "if the change is considered to be within the scope of the rule" in the first sentence may be confusing and may detract from the intent of the sentence. It is especially important not to use the phrase "within the scope of the rule" in guidance since, as stated in Section IV.A, one of the policy issues being considered is revision of the rule to better define the scope of the rule.</p> <p>As explained in Section III.A.4, if a proposed change meets the definition of a "change", then it is considered "to be within the scope of the rule". In other words, the phrase "if the change is considered to be within the scope of the rule" could be re-written as "if the change is considered to be a change". It would be clearer to delete this phrase in the first sentence and modify the second sentence to clarify its applicability to screenings, as described below.</p> <p>The second sentence appears to be referring to screenings, but uses the term "evaluations". The term "evaluations" should not be used because it may imply 50.59 evaluations (i. e., determination whether the proposed change requires prior NRC approval (an unreviewed safety question determination)) which is also used in the same paragraph. If this sentence is referring to screenings, change "evaluations" to "screening reviews" for clarity.</p> <p>Also, there is no statement that clearly states "Records of screenings are not required by 10 CFR 50.59". A guidance document on the implementation of 50.59 should contain this statement.</p> <p>The last sentence is not consistent with the previous sentence and is not consistent with Section II of this guidance. While all activities affecting quality are controlled under 10CFR App. B, determining whether a "change" is within the scope of 10 CFR 50.59 does not seem to satisfy this App. B quality criterion. Section II emphasizes the clear separation between evaluations of safety and 50.59 evaluations. Since 10 CFR 50, App. B requires all activities affecting quality to follow App. B rules, and evaluations of safety are different than evaluations under 50.59 (which determines only whether or not the change needs prior NRC approval), then screenings (which determine only whether a 50.59 evaluation should be conducted) should never constitute App. B records by themselves. This sentence confuses the separation between safety and 50.59, does not add valuable guidance to the screening discussion and should be deleted.</p>
<p>III.N.4, 1st paragraph, 3rd sentence</p>	<p>The phrase "Section 50.59 addresses the process for the licensee to make changes...." appears to be incorrect or misleading. 10 CFR 50.59 does not address the process for making changes, rather 50.59 addresses the allowance to make a change. As stated in Section I., Introduction, 50.59 is "a regulatory threshold to determine when NRC prior approval of a change is needed, rather than a safety or acceptability test." 10 CFR 50, App. B contains regulatory requirements related to all aspects of making changes at nuclear power plants including changes to the facility or procedures that are described in the SAR.</p>

Section	Comment
III.N.4, 1st paragraph, near middle	<p>The sentence that begins with "For example, if a licensee removes a system...." would be clarified if the removal process was clearly an App. B process rather than a 50.59 process. Recommend the beginning of the sentence be: "For example, if a licensee performs an Appendix B change to remove a system...."</p> <p>Also the sentence that begins with "Following issuance of a license amendment...." appears to be incomplete if it applies only to deleting USAR information. Suggest adding the phrase "to deleted or removed systems or information" after "conform" at the end of the sentence.</p>
III.N.4, 1st paragraph, last two sentences	<p>The term "licensing basis" is used several times, but it is not defined in the guidance document and does not appear to be used consistently, even in these two sentences (the modifying phrase "as described in the SAR" may apply to the first use, but not to the other uses).</p> <p>It is especially important not to use the phrase "licensing basis" in guidance since, as stated in Section IV.A, one of the policy issues being considered is revision of the rule to better define what is included in the licensing basis. Also as stated in Section I, Introduction, when discussing Millstone issues, "The lessons-learned task group concluded that (1) the concepts of current licensing basis and design bases are not clearly understood by some licensees and NRC staff; (2) both licensees and staff have difficulty identifying and locating bases documents; and (3) bases documents are not always appropriately used in NRC licensing and inspection activities and in licensee design and facility changes."</p> <p>Recommend not using the term "licensing basis", but rather use a phrase that clearly describes exactly what is being referred to.</p> <p>The last two sentences do not appear to relate to deleting USAR information. All processes that would evaluate and accept nonconforming conditions are required to follow Appendix B requirements, and seem to be covered by the examples discussed previously in the same paragraph. Therefore, recommend deleting these two sentences.</p>
III.O.4, and III.V.4, 3rd paragraph	<p>The wording of these paragraphs regarding compensatory actions may lead to conditions adverse to safety. It is WCNOC's position that compensatory measures should be allowed within the context of taking prompt corrective action consistent with the requirements of 10 CFR Part 50 Appendix B, Criterion XVI, Corrective Action. Not allowing compensatory actions during corrective action appears to be inconsistent with the guidance in section III.O.4, the third example circumstance used for clarification, which states "If the fix is planned for the next available opportunity, and that opportunity has not presented itself..., delay in implementation of the corrective action is acceptable if the licensee is making reasonable efforts to resolve the matter promptly. Under these conditions, assuming operability can be demonstrated, operation in a degraded or nonconforming condition may continue up to the next outage of reasonable duration and timing to effect the corrective action."</p> <p>In certain circumstances, if compensatory actions are allowed under this guidance, but those actions, even though they enhance overall safety, would involve a USQ, then the licensee would most likely choose not to take compensatory action rather than submit the proposed action as a license amendment request to the NRC for approval.</p>

Section	Comment
IV.A.3, 2nd paragraph	Recommend deleting the sentence "Thus, tying the scope of 10 CFR 50.59 to the SAR results in uneven application of 10 CFR 50.59." Although the information in various SARs is different, each plant is licensed based on the information contained in their SAR and 50.59 applies to that information, so the application of 50.59 is the same for all plants.
IV.A.3, last two paragraphs	<p>The phrases "upon which 10 CFR 50.59 governs the change process" in item (3) and "changes made pursuant to 10 CFR 50.59" in item (4) appear to imply that 10 CFR 50.59 controls or governs the change process. This is inconsistent with several other sections of the guidance which clearly state that 10 CFR 50.59 is an allowance to make the change and other regulatory requirements control the change process.</p> <p>WCNOC recommends changing the phrase in item (3) to "upon which 10 CFR 50.59 screening evaluations are performed" and the phrase in item (4) to "10 CFR 50.59 screening evaluations".</p>