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62 FR 24997
May 7, 1997

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June 26, 1997

Chief, Rules Review and Directive Branch
U.S. Nuclear Regulatory Commission
Washington D.C. 20555

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RULES & DIR. BRANCH
US NRC

Dear Sir:

Subject: Comments to Proposed Regulatory Guidance Related to NRC Letter SECY-97-035,
Implementation of 10 CFR 50.59 (Changes, Tests and Experiments).

The NRC recently issued SECY-97-035/NUREG-1060, Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests and Experiments), for comment as part of an initiative to provide better definition of the process for performing safety evaluations as described in 10 CFR 50.59. The Region IV Engineering Managers Working Group, which is composed of the top engineering management from the nuclear power plants within Region IV, undertook an effort to provide comments in support of this initiative. We believe that it is important for the industry and NRC to work together on such efforts.

Our attached comments represent the broad, collective majority opinion of the Region IV Engineering Managers. We hope you find these comments useful in your review of NUREG-1606. If you would like to discuss these comments with us, please feel free to contact me at (602) 393-5830, Tuesday through Friday, 7:00 AM to 5:30 PM PST.

Sincerely,

John H. Hesser, Chairperson
Region IV Engineering Managers Working Group
Palo Verde Nuclear Generating Station

Enclosures

cc: U.S. NRC Document Control Desk
Art Howell (NRC)
Chris Vandenburg (NRC)

ISP-11 Guides & Manuals
XL-4-1PT50.59

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**REGION IV ENGINEERING MANAGERS
WORKING GROUP**

COMMENTS ON:

SECY-97-035

**“PROPOSED REGULATORY GUIDANCE RELATED TO
IMPLEMENTATION OF 10CFR50.59
(CHANGES, TESTS AND EXPERIMENTS)”**

REGION IV ENGINEERING MANAGERS WORKING GROUP SECY-97-035 COMMENTS

Executive Summary

Under the auspices of the Region IV Engineering Managers Working Group, the Region IV utilities undertook an initiative to work collaboratively in reviewing SECY-97-035 and provide a set of integrated comments for the NRC's consideration. While detailed comments are attached for each portion of Attachments III and IV of the SECY-97-035 letter, there are some key issues and concerns that we want to highlight. We are concerned that some of the proposed regulatory guidance may result in some unintended consequences for both the NRC and utilities. We want to ensure that such potential ramifications are thoroughly and carefully discussed, understood, and appropriately addressed prior to taking any action.

SECY-97-035 represents a significant effort on the part of the NRC in trying to bring better definition to the 10CFR50.59 process. However, our strong belief is that the current 10CFR50.59 safety evaluation process has served both the NRC and the industry well over the past 30 years. We believe that the overall regulatory process for 10CFR50.59 evaluations is sound. However we also recognize that the issues that led to SECY-97-035 are not ones of an ineffective process, but rather ones of a few cases of ineffective implementation. To the extent that ineffective process implementation led to the SECY-97-035 letter, that should bear on the extent to which we change the 10CFR50.59 process.

Based on the SECY-97-035 letter it appears that the NRC agrees that when the NSAC-125/NEI 96-07 guidance has been implemented properly, its application has generally resulted in satisfactory safety evaluations. The industry attempted to improve on NSAC-125 through the development of draft guideline NEI 96-07, "Guidelines for 10CFR50.59 Safety Evaluations." We believe the industry is willing to work with the NRC to further revise NEI 96-07 to improve and enhance the 10CFR50.59 process. Consequently we believe it would be more effective for the NRC to work with the industry to build on NSAC-125/NEI 96-07 and to address the issues raised within the SECY-97-035 letter through such a process. The mutual goal would be for the NRC to endorse an appropriate revision of NSAC-125/NEI 96-07.

As the NRC itself indicates in the SECY-97-035 letter, just because a change involves a USQ does not necessarily mean that the change is not safe. Changes which can result in large increases in overall reactor safety can also still result in a USQ even though there may be a negligible increase in probability or consequences for the change. The NRC, in pursuing additional regulatory guidance or rulemaking in the 10CFR50.59 regime, should appreciate that determining that a change involves a USQ - even though it is safe - does provide a disincentive for a utility to pursue such changes. This occurs because of the schedular impact involved in requiring review and approval by the NRC and the burden applied by 10CFR50.90 amendment application for approval of a USQ. The overall guidance in the SECY-97-035 letter would exacerbate this situation by unnecessarily lowering the threshold for a USQ thus producing a step increase in the volume of USQs identified by the 50.59 process. We would also expect that the trend toward longer NRC review times for submittals would be exacerbated by an increase in the number of submittals under the proposed guidance contained in SECY-97-035. This could be counterproductive to reactor safety by discouraging licensees from pursuing plant enhancements as well as by diluting the resources available to licensees and the NRC. These same resources could otherwise be devoted to other issues of greater significance.

As written, SECY-97-035 represents a change in policy on the part of the NRC imposing new requirements. In addition, we believe that the guidance that results from the SECY-97-035 letter should also be considered under the backfit rule (10CFR50.109). SECY-97-035 should not be

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used today as an inspection standard until it is formally incorporated into the regulatory process. If the guidance of the SECY-97-035 letter is implemented, it should not be implemented retroactively. We would recommend that it become effective some period after its issuance so as to allow the NRC and licensees to change their processes and training programs to ensure consistent implementation. We would further recommend that the implementation period be agreed upon between utilities and the NRC, and be of no less than 180 days. Dependent upon the scope of changes to NSAC-125/NEI 96-07 agreed upon between the NRC and the industry, there may be a need for an even longer implementation period. To help ensure successful implementation of the revised guidance, the NRC should work with the industry to provide specific examples to illustrate the regulatory guidance to be established. Additionally, we would also recommend that the NRC assist implementation through holding workshops on this subject.

While we have provided extensive comments, there are some key points that we would like to highlight:

- Judgment - We do not believe that the regulatory process can be so clearly defined as to address all situations that a licensee or the NRC will encounter. The current 10CFR50.59 safety evaluation process relies on the effective use of management and engineering judgment in applying the regulations. Therefore, limiting the use of licensee judgment should be approached judiciously. However the SECY-97-035 letter appears to limit that use.
- Malfunctions - The NRC position which treats different causes of a failure as a malfunction of a different type diverts the focus of a safety evaluation from the effects of the malfunction. This position imposes a level of detail beyond the intent of 10CFR50.59 and represents a new regulatory position.
- Probability - By defining any increase in probability as a USQ, the NRC has established a requirement which will force changes which result in negligible increase in probability (i.e., no discernible or measurable increase) into the license amendment process with little or no added safety benefit.
- Consequences - The NRC position that any increase in consequences, even if the overall consequences are well below acceptance limits, results in a USQ is not consistent with established regulatory and industry practices and precedent.
- Margin of Safety - The acceptance limit for determining a margin of safety as currently defined by the NRC is overly restrictive and will result in unnecessary USQs that would be a burden on both the NRC and the industry. In addition, the scope of the documents to be reviewed is more conservative than established by the 10CFR50.59 regulation.
- FSAR Issues - The inability of licensees to remove extraneous or obsolete information from the FSAR without a 10CFR50.59 evaluation is burdensome with no safety benefit. Requiring 10CFR50.59 safety evaluations for these types of minor changes would divert resources that could be applied in other ways that would have a greater positive impact on plant safety.

We appreciated the opportunity to provide comments on the SECY-97-035 letter and recognize that it is a significant effort on the part of the NRC. However as written, we have some significant concerns that merit further review. We would be happy to meet with you to discuss these issues further.

Regulatory Issues

| Description | Page / line | Comments/Basis |
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| III.A Definition of Change | 5/39 | To clarify the wording of this section, it is recommended that "identical" be changed to "functionally identical." Terminology should be clear and unambiguous. Use of the word "something" is an example of imprecise communication that can lead to multiple interpretations of the guidance. Definition of terms should be provided as necessary to ensure clear understanding by the industry, regulator, and public alike (e.g., form, fit, and function). |
| | 5/44 | A change which would require a 50.59 evaluation must first modify or invalidate the information contained in the SAR. To determine whether a change alters the design, function, or method of performing the function of a SSC, NSAC 125 and NEI 96-07 states that a thorough understanding of the design basis of the systems involved are essential. Therefore, if the proposed change can be evaluated and documented in the screening to ensure the design bases and credited functions described in the SAR are not affected, the change should not require further analysis under 50.59. Regarding an "activity already reviewed" the guidance needs to also be clear on how one determines whether a prior submittal, reviewed and approved by the NRC, can be used to cover a proposed change being undertaken by a licensee and not require a 50.59 evaluation. |
| | 5/49 | <i>See General Comment #1 concerning items III.A and III.O.</i> Although SSC may have been modified in concert with maintenance activities, maintenance activities, per se, should not require a 50.59 review. The SECY-97-035 concerns are properly addressed through plant on-line maintenance programs, which account for operator experience and engineering judgment through the maintenance scheduling process. The intent of maintenance activities is to return the plant to its originally designed configuration and state. As such, there are no changes to plant configuration that should result from maintenance activities. <i>Comments relative to equipment left out of service for a long time are discussed in Section III.O of the comments.</i> |
| | 6/1-13 | The text provides a long list of what is considered when making a change. It should also provide a examples of what is not a change. Such a contrast will be very effective at reducing ambiguity. |
| | 6/5 | Removing a SSC from service, even if it is not discussed in the Tech Specs, should not, in itself, require a 50.59 review since the overall system operability is still reviewed by an SRO for impact on plant safety. However, a licensee has the obligation to ensure that removing equipment from service does not invalidate the design bases. By mandating a 50.59 for systems removed from service that are not covered by an LCO, the staff is requiring that Job/Work Orders be |

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| | 6/15 | <p>evaluated by 50.59. Allowance for routine maintenance is an inherent assumption in the design of any plant. In addition, the Maintenance Rule provides a mechanism to ensure that the impacts of removing equipment from service is evaluated. The draft guidance would paradoxically make it less burdensome to take TS equipment out of service under an LCO than to take non-TS equipment, which have a lower inherent safety significance, out of service. If the NRC elects to pursue this course of action and requires that a 50.59 be performed for systems removed from service, then License Controlled specifications need to be explicitly included under this definition of TS. The definition of SSC should explicitly include only safety-related items and systems in this context.</p> <p>This sentence should be clarified that implicit changes are to be reviewed as long as the potentially impacted SSC is explicitly discussed. In addition, SSC which have no impact on safety-related or important-to-safety SSC described in the SAR, should not require a 50.59 evaluation since the proposed change will always result in a negative USQ.</p> |
| III.B Definition of Facility | 7/7-9 7/44 | <p>This needs to be clarified such that one needs to consider SSC not described in the SAR only to the extent that could impact SSC described in the SAR through indirect or secondary effects. All 3 conditions referenced should be clear that this only considers information described in the SAR and not other engineering design information not discussed in the SAR. In addition, clarify that this includes the Licensing Basis.</p> <p>In section 50.2, Design Bases is defined as that information which identifies the specific functions to be performed by a structure, system or component of a facility, and the specific range of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system or component must meet its functional goals. Most U.S. plants were built using both design methodologies. The NRC has not always recognized the first definition and has enforced the quantitative approach. Again the information under 50.2 only includes design bases information to the extent it is described in the SAR. At the same time, all information contained within the FSAR does not constitute design basis information as defined under 50.2.</p> |
| III.C Definition of Proced. | 8/11 8/14 | <p>Changes to administrative procedures or administrative controls, such as organizational changes or review meetings, which do not have an affect on SSCs or the operation of the plant should not require a 50.59. There is no benefit to answering the questions defining a USQ for these types of negative impact activities.</p> <p>In reading the SECY, we are concerned that there is the implication that drawings in the SAR should reflect all plant operating modes and configurations. Note that SAR drawings generally do not describe how plant systems are operated. For example, valve alignments (open vs.</p> |

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| | | closed) will differ depending on whether the plant is in MODE 1 or shutdown. Licensees generally control system operation through System Operating Procedures, which are under the control of licensee 50.59 processes. The NRC should recognize this issue and clarify their guidance to acknowledge that operating a plant system differently than shown on SAR drawings (but within the bounds of plant licensing and design bases) does not necessarily reflect a change to the facility. |
| III.D Definition of Test or Experiment | 9/10 | Regarding section III.D.3, NSAC 125 and NEI 96-07 do provide guidance on defining tests and experiments. Specific discussion as to what is considered tests and experiments are found in these documents. For example, on page 4-6 of NSAC 125, a statement is made that "for preoperational tests, surveillance tests, functional tests and startup tests that are performed monthly, quarterly or on a refueling outage basis, safety evaluations are not required every time a test is performed". Four specific examples of tests that require safety evaluations are also provided. This same information is repeated in NEI 96-07 on pages 27 and 28. |
| | 9/26 | The "test or experiment" would typically involve a special procedure where plant systems are operated different from or in conflict with the description of system operations in the SAR. The context of this question should clearly recognize that the action is not within the scope of actions described in the SAR. The reference to a "special procedure for a particular purpose or an evolution performed to gather data" in the SECY is vague and does not account for the fact that the need for a 50.59 Evaluation is associated with how the equipment and/or plant is operated rather than the data which is being obtained during such operations. It is also requested that the NRC provide statements in this section that exclude nonsafety-related SSCs which have no direct or indirect impact on safety related or important to safety systems described in the SAR. For example many SARs describe the use of a potable water system. When changing a valve on such a system (i.e. within the power block) this change should not require a 50.59 evaluation. |
| III.E Definition of "as described" | 10/21 | The word "evaluated" should be "reviewed". The term "evaluated" implies a full USQ evaluation. The proposed action may not require a full evaluation. |
| | 10/42 | The NRC's broad interpretation of "as described" may potentially result in excessive 50.59 Evaluations on relatively trivial, non-significant changes which will not impact any conclusions reached in the SAR or NRC's conclusions. The NRC needs to clearly recognize provisions to allow licensees to screen out FSAR editorial changes, clarifications, and changes which have no impact on SSCs or plant safety, without having to perform a 50.59 evaluation. A specific example is a drawing only change (i.e. change to a P&ID) which does not affect the design, function, or method of performing the function of a SSC. Section 7.d in Part 9800 of the 1984 version of Inspection and Enforcement Manual specifically provides for such cases where 50.59 evaluations are not required. This |

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| | | discussion should be carried over to the NRC's current guidance. |
| III.F Definition of FSAR | 12/9 | No conclusion is reached by the Staff as whether information which is referenced in the FSAR (i.e. A-E topical, reports) are considered as FSAR information and would be subject to 10CFR50.59. It is believed that this information unless specifically extracted into the SAR text should not necessarily be classified as "FSAR". SAR descriptions may reference supporting documentation for information. It is proper to treat such documents as part of the SAR only to the extent they contain the information which is required for the SAR, rather than for clarity referencing information which is not required for the SAR but provides additional detail. Thus, to state that all references cited within the body of the SAR become part of the SAR may penalize those utilities who have provided useful information in the SAR. When we perform 10CFR50.59 evaluations, we review more than just the FSAR. The set of information that should be considered in performing a safety evaluation is addressed by NSAC-125. Thus, clarify the last sentence of the first paragraph in III.F.4 to recognize that the reference in the SAR must be evaluated to have relevancy before it is considered as part of the SAR (see section 4.1.1 of NSAC-125). <i>See also general comment #2.</i> |
| | 12/15 | Additional guidance should be provided on the information in the SAR which is outside the scope of 10CFR50.59, e.g., similar to the area population data given as an example in the SECY. |
| | 12/31 | The NRC as a part of SECY 97-036 should define cases where updates to the SAR are expected, i.e., this should be explicitly called out in NRC Generic Letters or Bulletins requesting the licensee to perform analyses. |
| III.G Industry Use of Screening Process | 13/28 | The basis for screening is to determine whether a detailed 50.59 is required. Screening for a USQ is inappropriate considering that the purpose of performing a 50.59 is to determine if the activity is a USQ or not. The word "USQ" at the end of the sentence should be changed to "evaluation". |
| | 13/34 | The statement "wherever in the plant" should be replaced by "in the facility." |
| | 14/19 | The guidance states that screening evaluations might constitute records of activities affecting quality. If screenings are performed within the utility's processes, we recommend that the screening be retained consistent with the retention requirements of the document being screened. |
| III.H Definition of Accident Previously Evaluated | 15/12 | The SECY considers all events evaluated in the FSAR beyond the Chapter 15 accidents to be "accidents". Typically, only those accidents contained in Chapters 2 (as appropriate), 6 and 15 are considered accidents that would be addressed under the USQ questions dealing with probability, consequences and accidents of a different kind. The other events should be considered malfunctions of equipment that would be evaluated under the malfunction of equipment USQ questions. Recognizing that the same conclusion would be reached, it would be reached under a more accurate |

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| | 15/31 | <p>definition and a more appropriate application.</p> <p>We recognize that as stated in SECY 97-035, the staff will be providing additional guidance. We recommend that the NRC clearly distinguish between accidents and malfunctions to avoid confusion in the response to questions and potential enforcement concerns.</p> |
| III.I Malfunction of equipment ITS of a different type | 16/34 | The expanded definition of malfunction is not necessary because this is prevented by good engineering practice. |
| | 17/28 | <p>The NRC requests that licensees also evaluate the potential cause of a malfunction as a condition that would be a USQ, this could substantially expand the actions that would require NRC review, thus diverting the safety focus of the NRC and utilities by overly complicating the regulatory process. In accordance with the guidance contained in SECY 97-035, if the new component functions differently but results in the same probability or consequences, then this would be a USQ¹. The determination as to whether a USQ exists is whether a different "type" of malfunction exists or not. If a component's potential failure can propagate to other systems or components is the concern and not the cause.</p> <p>In addition, postulated, non-mechanistic failures of non-safety as well as safety-related equipment are typically assumed in SAR analyses. Exact failure modes are typically not specified. These modes should not be addressed unless specifically addressed in the SAR. This is consistent with the definition of design basis under 10CFR50.2 which <u>defines</u> a safety function as opposed to <u>how</u> the function is performed.</p> <p>Therefore, we disagree with the NRC approach to categorically treat different causes of failure as a failure of a different type than that evaluated in the SAR. This does not provide a reasonable regulatory basis for the definition. Equipment malfunctions should be treated based upon the effects of the malfunction, given that probability or consequences of the malfunction do not increase. The proposed guidance appears to confuse the significance of component failure mechanism with that of failure mode. A new failure mechanism is not necessarily a "new type of malfunction" unless it results in a new failure mode of the equipment or system. NSAC-125 and NEI 96-07 take a proper approach to this subject. This represents a new requirement as discussed in the cover letter.</p> <p>The proposed regulatory guidance is also counter to the increased NRC interest in Performance Based Regulation. The overall results and performance of the equipment must be assessed; if a different failure mode results in no different failure impacts to the rest of the plant, then</p> |

¹ We believe that literal compliance with the SECY-97-035 guidance would preclude virtually any procedure change since although the function performed by the procedure remains unchanged, the procedure steps are now changed. Similarly, the SECY-97-035 guidance would limit licensees to identical component replacements.

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| | 17/36 | there is no change in the performance of the equipment in question, or upon any other SSC influenced by the subject equipment. |
| | 17/13 | <p>The example provided by the NRC is an inappropriate example. If a pressure transmitter fails, what is of interest is if that pressure transmitter can fail in a manner that propagates to other systems in a new or different way, rather than merely the mode of failure. However, such a failure, if there are no different effects on other equipment, does not influence plant response and does not influence the response of any SSC important to safety, then it is improper to categorize this as a failure of a different type than that described in the SAR. The NRC typically did not perform their safety review on a component level basis using the pressure transmitter as an example, rather they performed it on a system level. Many design changes involve adding new components or replacing existing components with improved designs or new materials. There may be new causes of failures associated with these components, that by the new NRC definition, would be a USQ. This level of detail appears to be beyond the intent of the 50.59 rule and certainly would limit changes which could be made without prior NRC approval.</p> <p>The fourth and fifth paragraphs of III.I.4 should be modified, to reflect the above approach.</p> |
| III.J Mods associated w/Tech Specs | 18/30 | Agree that any "proposed" modification associated with a Tech Spec should receive a license amendment. However, it should be clear that compensatory actions associated with finding a Tech Spec that is not conservative should be allowed while a TS amendment is being processed by the licensee and reviewed by the NRC as long as appropriate administrative controls are in place. (See item III.L.) |
| | 18/35 | The statement that "...staff approval of the proposed modification (and TS) must occur before the ongoing modification is implemented" does not allow for planning implementation of these changes. If an activity is determined to require a TS change or involve a USQ, the activity is generally held until the NRC approves the change or other dispensation is received. With an adequate 50.59 screening/evaluation and design requirements review, a modification should be allowed to be designed, planned, installed, and tested prior to TS approval by the NRC. When the TS is NRC approved, NRC then cannot hold Licensee in violation (compliance issue) of License/TS until the modification is placed in service/ declared operable, per the licensee's implementation schedule. The 50.59 for the change must address the basis for the controls established and verify that no potential unreviewed safety question exists for the interim condition. |
| III.K 50.59 Evals for Generic Mods | | No comment |
| III.L Tech Specs Not Adequate | 20/10 | It should be clear that compensatory actions associated with finding a Tech Spec that is not conservative (e.g., new analysis demonstrates a higher |

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| for Design Bases | | <p>required flow than specified per TS) should be allowed while a TS amendment is being processed by the licensee and reviewed by the NRC as long as appropriate administrative controls are in place. If a degraded condition (e.g., compensatory action is required as a result of heat exchanger fouling) is identified, and a successful operability evaluation has been performed, and the timing is such that a unit is approaching an outage or other period where the condition will be corrected, there should not be a need to temporarily modify the TS to document the compensatory action. If it is determined that the technical specifications will require modification to resolve the nonconservatism in the Specs, the licensee should pursue a "timely" TS change with the NRC. Unless there is an operability issue, there should be no urgency in addressing a nonconservative technical specification provided that administrative controls are in place. A licensee who is pursuing Improved Technical Specifications should also be allowed to correct the condition through this process. <i>See also Item III.O on Degraded and Nonconforming Conditions.</i></p> <p>20/14 The NRC has issued related guidance in GL 91-18 on evaluation for operability. The first action is to write a Condition Report (nonconformance report) which will ensure that the condition is identified and will provide for a 10CFR50.72/.73 review. It is agreed that the Tech Specs should be changed, however, there is no basis in safety that this would require an immediate action. The actions resulting from the condition report may involve additional design changes that will provide a different Tech Spec action and Bases. There is also the potential that other actions which may be a refueling cycle away that will return the condition to its required status. These do not require a Tech Spec change.</p> |
| III.M PRAs in 50.59 Evals | <p>21/3</p> <p>21/12</p> <p>21/19</p> | <p>The discussion in the SECY does not acknowledge the general industry practice of maintaining living PSA's for their plant. The second sentence in the first paragraph under III.M.4 should be deleted.</p> <p>The statements by the NRC in this paragraph with regards to use of deterministic methods and postulated design basis events appears to reach a conclusion that is different than that contained in section III.P. Section III.P seems to come to the conclusion that any change in probability including any minor movement within a broader accident category is a USQ and no allowance can be taken from the broader deterministic conclusions contained in the SARs. <i>See further comments under Section III.P</i></p> <p>PRAs may not be the appropriate tool for determining whether a USQ exists, but it does provide a potential benefit for characterizing the potential change in probability if a USQ has been determined to exist. This should not be inferred that PRAs cannot be used, but only that they may not represent the best tool. PRA results and risk insights can play a significant role in evaluating a potential USQ. Risk insights on the proposed change could also provide an additional dimension to the</p> |

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| | | <p>safety test of the 50.59 process relative to the purely deterministic perspective.</p> <p>Note: The potential role of PSA in determining when overall impact on nuclear safety should be acceptable without NRC review (e.g., where there is a very small increase in probability combined with a great decrease in consequences, or vice versa) in a risk-informed arena should be discussed. The NRC is sending a mixed message to the industry on use and acceptability of PSAs for risk informed decisions. The NRC needs to better clarify the specific concern of PSA application here without discounting the valuable uses of PSAs in today's safety perspective.</p> |
| III.N Deleting Information from FSAR | <p>All</p> <p>23/20</p> <p>23/38</p> | <p>The NRC staff position for not allowing removal of information from the SAR is overly conservative, not well justified and not technically based given the burdens placed on licensees resources that would otherwise be available to be focused on areas of higher safety significance. It is reasonable to believe that not all information that is contained in the SARs were used to establish the basis for the O.L.. In addition, later vintage plants generally contain more general information that does not effect safety. To not allow any information to be removed from the scope of 50.59 reviews is not effective in truly addressing those portions of the SAR which should receive a 50.59 evaluation versus those that only provide general plant descriptions. An example would be a SAR drawing could not be allowed to have non-technical detail removed simply because it was in the SAR. We believe that the NRC perspective represents a new requirement.</p> <p>When excessive detail has been placed in a SAR, this can increase the burden upon both NRC and industry. NRC needs to allow for SAR streamlining, particularly for more recent vintage plants that have a large cross-section of detail in the SAR. NRC has Standard Review Plans (SRPs) and Regulatory Guides that describe what information should be contained in a SAR. [There are licensees whose detail goes beyond that which is required by R.G. 1.70 or the SRPs]. NRC should endorse the concept that plants should be able to remove excess detail which is not required per RG 1.70 or NUREG-0800 from a SAR, recognizing that not all plants are committed to RG 1.70 or NUREG-0800.</p> <p>We acknowledge there is validity to the concern that removal of information from SAR should be approached with caution. We are confident our processes, including 50.59 processes, are adequate to prevent removing information which would impact the reliability and accuracy of future USQ determinations.</p> <p>Recognizing the reference to GL 80-110 for not deleting information from the SAR, it is inconsistent with a desire for SAR value and increases burden. If the SAR is to be a vital, living document, then there is no need to maintain no longer applicable information concerning initial training programs and preoperational test programs in it. The additional</p> |

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| | | <p>information can dilute the safety focus of the SAR and impose additional burden to update extraneous information.</p> <p>If the NRC continues to adhere to the position that no information can be deleted from the FSAR, the NRC should proceed with rulemaking and provide guidance which would allow licensees to not be required to conduct 50.59 reviews on specified portions of the SAR that have no regulatory or safety impact. Again, performance of low value 50.59 reviews and updating of extraneous SAR information is resource intensive and costly with minimal safety benefit.</p> |
| III.O 50.59s on Degraded/ Nonconforming Conditions | 26/28 | <p>CIRCUMSTANCE (1): We support the SECY position that compensatory actions taken to address nonconforming conditions should, in and of themselves, be acceptable under 10CFR50.59 on a stand-alone basis. If such compensatory actions are not already fully addressed under existing 50.59 reviews, additional 50.59 reviews should be performed for the compensatory actions. Such 50.59 reviews need only consider that portion of the activity that involves the compensatory action and not the full scope of the concern. Clearly conservative compensatory actions that place the plant in a safer condition can be implemented while the 50.59 for such compensatory actions is being prepared. We believe no other 50.59 reviews are needed at this time.</p> |
| | 26/36 | <p>CIRCUMSTANCE (2): Agreed.</p> |
| | 27/1 | <p>CIRCUMSTANCE (3): <i>See General Comment #1 concerning Degraded and Nonconforming.</i></p> <p>We acknowledge that the policy of conducting 50.59 reviews (in addition to GL 91-18 operability evaluations) on long standing degraded conditions is a conservative action based on our discussions in General Comment #1.</p> |
| | 27/12 | <p>Additionally, We believe that the nonconforming condition should be corrected at the first available planned maintenance opportunity of sufficient lead time and duration commensurate with prudent and practical plant maintenance scheduling processes to include considerations for risk and availability.</p> |
| | 27/46 | <p>Of particular concern is not allowing a plant to restart with a degraded condition involving a potential USQ is not regulatory based unless the action is prohibited by technical specifications or involves an operability concern. A request for NRC review of the USQ should be expeditiously pursued. The existence of a USQ does not mean that a safety issue exists, but only that NRC review is required. The licensee would have to first show that the condition is not a safety or Operability issue that warrants continued plant shutdown. Otherwise, all other cases where a USQ exists would not require a licensee to remain shutdown. For example, a condition may occur during an outage or shortly before an outage which would not impact operability but where the parts required for full restoration may not be available until after the planned startup.</p> |

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| | 27/45 | <p>Any regulatory guidance needs to recognize that for such circumstances, where of low risk/safety significance, the first outage is not the first available opportunity to restore the component.</p> <p>The requirement to submit a License Amendment request expeditiously, i.e., within days, is overly restrictive and unnecessary. We recommend that the requirement be to submit a License Amendment in a timely manner commensurate with safety. Prudent licensee action should be to expeditiously inform the NRC of the existence of any USQ.</p> |
| III.P Increase in Probability of Occurrence | 28/36 | We endorse the concept of compensatory measures to deal with the issue of Probability of Accidents as described in "Use of Compensatory Measures in the 50.59 Process," one of the point papers submitted to the NRC via NEI correspondence (Project No. 689) of October 24, 1996. |
| | 28/45 | The NRC position to invoke that "any" increase in probability as a USQ is not consistent with how the rule has been historically applied by both the NRC and licensees. Note that measurement uncertainties are involved in any process. Hence, when the NRC originally promulgated 10CFR50.59, inherent in the rule was the fact that any increase in probability or consequences had to be a measurable one. Any increase which was not negligible which could not be measured was considered to not be an increase, as recognized by the NSAC-125 guidance. It remained the licensee's responsibility to ensure that combinations of negligible increases also remained negligible, i.e., no discernible or measurable change. |
| | 29/16 -40 | The discussion provided in this section of the SECY is confusing as to determining whether a probability increase has occurred. Probability changes should only be a consideration if there is a definitive change in occurrence that would actually indicate a probability change. During this time frame, probabilities were considered in the four categories of ANSI N18.2 (currently ANSI N 51.1). To consider any increase would represent a new NRC position and should require backfitting consideration. This section seems to conflict with section III.M which provides the proper approach to determining a USQ. III.M clearly indicates that deterministic approaches are appropriate which would conclude that potential minor perceived probability changes could not be reached if the measuring stick is good engineering judgment and not specific probabilities. The NRC Staff discussion on page 29, lines 16-36 is the proper interpretation. <i>[NRC should also provide examples for clarification]</i> |
| | General | We agree that if permanent administrative controls are required to comply with the licensing basis/SAR and the intent of the existing SAR text is modified, the administrative controls should be added to the LBD/SAR. The NRC should also provide clarification that the addition of components or piping within a system installed consistent with current codes, standards, analysis, etc. does not necessarily constitute an increase in probability of occurrence of accident or equipment malfunction. Not clearly stating this philosophy in the NRC guidance may cause enforcement actions for |

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| | | everyday design changes that have no USQ potential. |
| III.Q Probability Still w/ Design Basis | 31/4 | The approach proposed here by the NRC is acceptable and the same philosophy should be applied to the definitions of "Consequences" and of "Margin of Safety" in the draft regulatory guidance. |
| | 31/21 | <p>The examples used by the NRC (e.g. turbine missile) make it appear that the probability of an accident may increase from the existing level to a level that is still below the specified criteria, and not be considered an increase in probability. Again we believe that this approach is appropriate, however, this appears to conflict with the guidance in section III.P and is inconsistent with the approach to consequences as discussed in section III. R.</p> <p>In example (a), the NRC states that reducing the capability to withstand an earthquake, but maintaining the capability above the design basis, need not be considered an increase in the probability of an accident. The commentators believe that the capability of a SSC to withstand an earthquake does not affect the probability of the accident; the malfunction of equipment can be affected by the seismic design capability of a SSC, but not the initiation of the accident.</p> |
| III.R Increase in Consequences | 32/42 | <p>NRC is improperly treating use of design margin as an increase in Consequences in Section III.R. Any increase in consequences must be with respect to NRC imposed acceptance limits, specifically those in the Standard Review Plan or in a plant SER. As written, there is ambiguity in this phrase as to the exact nature of the qualifier "previously evaluated in the SAR." Past industry and regulatory practice and precedent has clearly established that the term does not refer to an increase in the values documented in the SAR. Specifically, focusing on consequences solely, the rule asks, for an accident or malfunction of equipment important to safety previously evaluated in the SAR, if there is an increase in consequences. The rule does not establish the SAR reported dose values as the baseline for such an increase. This is clearly demonstrated in the NRC SERs for numerous plants, which have stated the results submitted by licensees are acceptable because they are less than 10CFR100 limits, or less than some specific limit calculated by the NRC for the specific plant and event. The NRC promulgation of acceptance criteria in accident analyses different from the values submitted by licensees in the SAR is <i>de facto</i> acceptance that the SAR is not the baseline upon which to judge if changes to dose consequences are acceptable.</p> <p><i>See General Comments Discussion Item 4 below regarding Consequences</i></p> |
| III.S Reduction in Margin of Safety | 34/15 -23 | Acceptance limits should not necessarily or in general be the values for calculated performance which are documented in the SAR. The acceptance limits should be the values which are the NRC acceptance limits per the regulatory guidance/SER. Any regulatory guidance needs to differentiate between "Margin of Safety" and "operating margin," which the current proposal does not. If the scope of the "margin" question is at |

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| | | <p>the currently proposed criteria, any value that has been established in the SAR that reflects an established limit will be considered a margin that would represent a USQ. This would create a significant increase in USQ that would require NRC review.</p> <p>In addition, to tie any margin of safety to values in the SAR would be counterproductive to NRC's interest in SAR integrity. Plants who have provided accurate and detailed information in their SAR would be penalized under the draft guidance, as any use of the design margin between what is reported in the SAR and the regulatory guidance/SER acceptance limits would result in a USQ. The regulatory guidance should serve as a basis for acceptance limits, not values which are merely documented within the SAR or SER. The licensee should be able to use applicable regulatory guidance (e.g., Reg. Guides) to determine proper acceptance limits when evaluating changes to the facility.</p> <p>Use of SAR values for determining the basis for margin of safety is a new requirement subject to rulemaking, not an interpretation of existing requirements.</p> <p>The containment pressure example used in Figure 3-2 of NSAC 125 provides a good example. The difference between the containment failure point and the analyzed maximum operating "acceptance limit" is the margin of safety (if it is discussed in the bases of the Tech Specs). Any value discussed below the acceptance limit value (such as a peak pressurization value) would establish only an operating margin, and would not be subject to a USQ.</p> <p>The application for determining "Margin of Safety" in NSAC 125, section 3.8 should be endorsed by the NRC.</p> <p>We also believe these comments also apply to NRC Inspection Manual Part 9900: 10 CFR Guidance.</p> |
| III.T Scope of Basis for Any Tech Spec | 37/25 | NSAC 125/ NEI 96-07 guidelines apply a broader interpretation than the strict regulatory requirement to the term "basis." This position is an optional application approach that is conservative. Licensees can take the more conservative approach to include the SAR and other licensing basis documents. However, the application of information outside the Bases of the TS is not legally binding. Thus, NSAC 125/ NEI 96-07 has represented a more conservative approach over the 50.59 rule. |
| | 38/5 | The NRC's basis for expanding the scope of the margin of safety beyond that contained in the Bases of the TS is not founded in the original rulemaking. The clear original intent of the rule applies only to the Technical Specification Bases only. (See attached Margin of Safety Background Paper). |
| | 38/14 | At the end of the second paragraph in III.T.4, it should be noted that while Tech Spec Bases do not consistently define margins of safety, it must also be recognized that the Technical Specifications themselves do have |

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| | | <p>an internal consistency in regulating reactor safety. This lack of consistency is what has driven utility efforts, such as that within the CEOG, to reexamine Allowed Outage Times within Technical Specifications and to apply risk insights to improve Technical Specifications. Even though the level of information contained in the Bases of the TS have varied from licensee to licensee and over time, the intent of the original regulations are specifically intended to be the Bases of the TS. However, with the application of the new revised standard TS, the content of the Bases are more focused on supporting what is considered important and what information would establish a margin of safety that the NRC would consider within the scope of needing NRC review to change as a USQ.</p> |
| | 38/23 | <p>The previous position taken in Inspection Manual Chapter 9900 is the proper regulatory position for the margin review scope and should remain.</p> |
| III.U Application of New Methods for USQ | 39/36 | <p>In the period since most plants were licensed, there have been advances in technologies and methodologies which allow licensees to better analyze the design of SSCs and plant operation. If the new methodologies are standard to other industries and are generally accepted practices, their use should not be defined as a USQ.</p> <p>Few methodologies require explicit NRC approval, for example, those used for compliance with 10CFR50.46. In cases where the SER specifically calls out use of approved methodology as one of the bases for NRC approval, use of alternate methodology would have to be evaluated against the SER. If the new methodology is consistent with these criteria (e.g., includes features required by the appropriate regulatory guidance), then the change should be permissible under 50.59.</p> <p>There should be a significant difference in the treatment of a methodology under 10CFR50.59 depending on the nature, complexity, and safety significance of the application of that methodology. While methodologies for Chapter 15 NSSS and core analyses require explicit NRC approval, and codes used for certain structural analyses are required to be documented within Chapter 3 of the SAR, the requirements for methodologies on other subjects (e.g., room heatup, radiological releases) are less stringent. In such cases, whatever methodology is used must be properly and thoroughly qualified and undergo verification and validation, but a change in methodology is not inherently in and of itself a potential USQ. Changes in input assumptions or analysis assumptions must be addressed within the format of 10CFR50.59, but would not be USQs if they continue to meet the appropriate acceptance criteria of the SRP, SERs, Regulatory Guides, etc.</p> <p>To apply the methodology to the old design as well as the new design to determine that a USQ is not involved is not necessary if the new design continues to meet the licensing and design basis as defined for the SSC. The point should be to ensure that acceptance limits are met, rather than</p> |

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| | 40/8 | <p>to do a strict comparison between methodologies applied within calculations.</p> <p>The staff does not review and approve methodologies for all analyses which are included within the SAR as implied in the last paragraph of III.U.4. This discussion needs to be modified or deleted. Appropriate software control programs ensure that software used to support licensee analyses is adequate for its purpose where explicit NRC approval is not required.</p> |
| III.V Use of Compensating Actions for USQ | 41/16 | The term "clearly outweighs" is a judgment call since one is making a deterministic evaluation as to offsetting or compensating affects. The NRC needs to add discussion to this section to provide adequate latitude for good engineering judgment to avoid enforcement action. |
| | 41/23 | <p>We find the proposed NRC guidance confusing relative to the linking of proposed changes. NRC should endorse the guidance offered in NEI 96-07. It is reasonable and proper to account for the impact of compensatory actions as a means to counterbalance any potential negligible increase in probabilities or consequences, provided that the compensatory actions can stand on their own. The compensatory action may need to be subject to a separate 10CFR50.59 review to demonstrate this. [If permanent administrative controls are required to comply with the licensing basis/SAR and the intent of the existing SAR text is modified, the administrative controls should be added to the LBD/SAR.]</p> <p>We are unable to agree with the NRC discussion concerning linking various changes since that discussion is not of sufficient clarity. Any such discussion should be supplemented by examples to clearly outline NRC's views on this subject.</p> |

Policy Issues

| Description | Page / line | Comments/Basis |
|--|-------------|---|
| IV.A | | The scope of what should be included in the SAR is within the scope of 10CFR50.71(e) and should be addressed under the actions for SECY-97-036 and not this SECY. |
| IV.B | | <p>This is consistent with the thinking discussed in the second paragraph of B.3, "<u>Other Options</u>." An approach which would allow for implementation of non-risk significant USQs without prior NRC approval (but possibly with prompt NRC notification) could be in the best interest of licensees, the NRC, and, through more focus on nuclear safety, the public.</p> <p>Item B.2: The industry does not believe that industry guidance (NSAC 125/NEI 96-07) provides interpretations which are inconsistent with the requirements of 10CFR50.59.</p> <p>Item B.3, "<u>Increase in Consequences</u>": We disagree with the NRC interpretation that any increase in radiological consequences above the value calculated in the SAR is a USQ. (see III.R discussion). We do not think that rulemaking is necessary to clarify that the purpose of 10CFR50.59 is to ensure that consequences remain within acceptance criteria, i.e., those spelled out in the SERs or other regulatory guidance.</p> <p>Item B.3, "<u>Margin of Safety</u>": The thought process in the first paragraph should also be that applied to the definition of radiological consequences, i.e., the SER or other regulatory guidance provides the acceptance criteria, not the value documented in the SAR.</p> |
| [Other] Changes Required by 10CFR50.90 | NEW | Rulemaking to delete the 10CFR50.90 requirements for a USQ approval should be pursued. The application of 10CFR50.90 is overly burdensome on the NRC as well as the licensee. A simpler process requiring only NRC review and approval without license modification is more appropriate. <i>See Item 3 under attached General Comments.</i> |

GENERAL COMMENTS:

1. **DEGRADED AND NONCONFORMING** - The NRC in sections III.A and III.O of SECY-97-035 discusses the concept of a "de facto change or modification." It appears the NRC's concern is that licensees may inappropriately use their prioritization and scheduling prerogatives to delay corrective actions and maintenance activities necessary to restore an identified condition of being outside of the licensee's licensing basis to a condition of being within the licensing basis. We believe that the NRC already has sufficient regulatory authority to deal with what is essentially a timeliness of corrective action issue via the application of 10CFR Appendix B criterion 16 and does not need to create a new category of change or modification to make 10CFR50.59 apply to the timeliness of corrective actions. Furthermore, we believe that the history of application of 10CFR Appendix B Criterion 16 supports that the NRC has shown no reluctance in using this criteria. Nevertheless, we believe the guidance in SECY-97-035 in Sections III.A and III.O associated with the *de facto* changes, as augmented by our comments, provides useful input to the industry and the NRC as to what constitutes timeliness of corrective actions and maintenance activities.
2. **SAR REDUCTION** - It is believed that not all aspects of the FSAR should require a 50.59 evaluation just because the SAR changes. Many areas within the FSAR contain only descriptive information that will have no impact on the NRC's decision based on the questions asked by 10CFR50.59 (i.e. the review will always result in a negative USQ conclusion). Other cases may involve only clerical changes that will not impact the conclusion and should not invoke a complete 50.59 evaluation. In addition, FSARs typically contain P&IDs that include detail that is beyond a concern with the designed function and operation of the systems. The 50.59 evaluation process should be a limited review where the potential for safety analysis or a true USQ is potentially at risk. The NRC Staff should provide considerations where certain changes which will obviously not result in a USQ can be exercised. Deletion of existing information which is believed to be below the level of detail required to be included in the FSAR. Such deletions should meet the following criteria.

Information contained in the SAR:

- Was not specifically required to be included by regulatory requirements/guidance (e.g., 10CFR50.71(e), Standard Review Plan, Regulatory guides, etc.,
- Was not the basis for any commitment,
- Was not believed to be the basis for NRC acceptance in any SER/SSER,
- Provides safety or safe shutdown aspects of details (if any) are covered by an existing broader or more general commitment (e.g., commitment to a Reg Guide or industry standard,
- Is contained in a more appropriate location than the SAR.

We recommend that the staff and NEI use this as an appropriate starting point.

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3. **APPLICATION OF 50.59 FOR USQ APPROVAL** - 10CFR50.59(c) requires that a licensee who desires to make a change to the technical specifications or to request NRC approval of a proposed change that involves an unreviewed safety question, shall submit an application for license amendment under 10CFR50.90. The action to request an amendment to the license is applicable for a change to a technical specification, but not a USQ. A change to the SAR which would require NRC approval is not directly applicable to the license, but only the supporting documents (i.e. SAR). To require an amendment under 50.90 requires that some portion of the license be changed. No part of the license deals with the a change which is being made to the SAR. Similar to that which was proposed during initial licensing of the plants, a request for a SAR change should be nothing more than a request to review and approve a change to the SAR given a justifiable basis. The accuracy of the information provided to the NRC would still be within the requirements of 10CFR50.9 enforcement without imposing a 50.90 amendment process. The more stringent actions of 50.90 would slow the approval process with no commensurate level of safety. Rulemaking should be performed to simplify the process if a USQ is identified which is desired.
4. **CONSEQUENCES** - To tie any increase in consequences solely to values in the SAR would be counterproductive to NRC's interest in SAR integrity. Plants who have provided accurate and detailed information in their SAR would be penalized under the draft guidance, as any use of the design margin between what is reported in the SAR and the SER/regulatory guidance acceptance limits would result in a USQ. However, plants who have maintained information in their SAR which, for example, merely repeated that dose consequences met the appropriate requirement (e.g., < 10CFR100, less than a small fraction of 10CFR100, less than GDC 19 limits) would be allowed to continue to use design margin between their actual calculated values and the values reported in the SAR without having to go through NRC review and without the burden of the additional processing required for changes involving USQs.

NRC agreement with the fact that the SAR is not the baseline for determining if there is an increase in consequences is documented in the May 10, 1989, NRC letter from C.E. Rossi to Mr. T.E. Tipton of NUMARC. In this letter, the NRC states that

"if a proposed change, test, or experiment, would result in an increase in dose from an accident or equipment malfunction above that previously reviewed and approved by the staff as part of the licensing basis for the plant (i.e., the acceptance limit), then the proposed change, test or experiment involves an unreviewed safety question and would require prior NRC approval."

The NRC also states in this letter:

"...if in licensing the plant the staff explicitly found that the plant's response to a particular event was acceptable because the dose was less than the SRP guidelines (without further qualification) then the staff implicitly accepted the SRP guideline as the licensing basis for the plant and the particular event, and the licensee may make changes that increase the consequences for the particular event, up to this value without NRC approval. However, if the staff cited some value other than the SRP guideline as its criteria for licensing the plant then that value is considered the licensing basis for the plant."

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Thus, the NRC has clearly established that the acceptance basis in the SER, which is often that of the SRP, is the proper licensing basis for the plant. Thus, any value for the dose consequences which remains less than that acceptance basis has been reviewed by the NRC as within the plant licensing basis, hence is not a Unreviewed Safety Question².

NRC should explicitly allow use of improved technology or improved data which is approved at one plant or used within NRC rulemaking to be used at other plants without it being a USQ. For example, use of ICRP30 dose conversion factors by a plant previously using older ICRP 2 factors, which have proven inaccurate and overly conservative, should be acceptable for all licensees since the NRC has inherently accepted ICRP 30 by using it as the basis for 10CFR20.

² Note: an example exists where NRC has explicitly used the SRP alone as the basis for limits on a plants licensing basis. In 1992, a PWR submitted to the NRC, as a potential Unreviewed Safety Question, a case where the calculated percent of fuel rods experiencing DNB as the result of a transient analysis exceeded the value previously documented in its SAR and SER. The SER had repeated the results of the utility analysis and had concluded, without an explicit basis, that the results were acceptable. Since there was no clear acceptance basis discussed in the SER, the utility had submitted this case to the NRC as a potential USQ. The NRC responded to the utility and stated that

"However, even if all of the pins experiencing DNB were to fail, a coolable geometry would be maintained and the consequences remain a small part (less than 10 percent) of 10CFR Part 100 limits."

Note that the SRP acceptance limits for this event are that the dose consequences remain a small part (less than 10 percent) of 10CFR100 limits.

The staff also concluded that the 10CFR50.59 criteria had been met for this change and that the change satisfied 10CFR50.59 criteria.

BACKGROUND PAPER
10CFR50.59 MARGIN TO SAFETY QUESTION

10CFR50.59 Regulation (abbreviated):

10CFR50.59 paragraph (a)(1) specifically allows: "(a)(1) The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question."

Paragraph (a)(2) defines the unreviewed safety question as follows: "A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced."

Concern:

In determining whether an unreviewed safety question exists per the criteria of paragraph (a)(2) of the regulation, the license basis document that must be reviewed to determine if the "margin of safety" is reduced must be clearly understood. The document establishing the existence of a margin of safety is the Bases portion of the technical specifications. NRC Inspection Manual Part 9900: "10CFR50.59; Interim Guidance on the Requirements Related to Changes to Facilities, Procedures and Tests (Experiments)" and SECY-97-035 states "that the licensee should first look to the bases for the particular TS. If a margin of safety is contained in the bases of the TS, any reduction in that margin must be considered a reduction in the margin of safety, and not allowed under the 50.59 process. If the TS Bases do not specifically address margin of safety, then the licensee's safety analysis report, the staff's safety evaluation report (SER) and appropriate other licensing basis documents should be reviewed to determine if the proposed change, test, or experiment would result in a reduction in the margin of safety. In each case, a determination must be made to establish what constitutes the original licensing basis."¹

Regulatory Background:

Before December 17, 1968, the definition of unreviewed safety question in 10CFR50.59 did not include the "margin of safety" portion. For that matter, before that date the technical specifications did not have Bases sections. The change that added both of these had been proposed on August 16, 1966, as part of a larger revamping of the contents of the technical specifications to reduce the level of detail in the technical specifications. This revamping of the contents of the technical specifications involved deleting 10CFR50 Appendix A which had been issued in 1962 to provide guidance as to matters the AEC generally expected to be covered by technical specifications, providing two new guidance documents outside the realm of 10CFR ("Guide for the Organization and Contents of Safety Analysis Reports for Nuclear Reactors" and "Guide to Content of Technical Specifications for Nuclear Reactors"), adding a new 10CFR50.34 requirement to file a preliminary safety analysis report with an application for a construction permit and additional 10CFR50.34 requirements regarding the content of the final safety analysis report.

It was also part of this major modification of the reactor licensing process that the current system of technical specification content involving the safety limits and limiting safety system settings, LCOs, surveillance requirements, design features, and administrative controls was set forth in 10CFR50.36. As part of this change to 10CFR50.36, a requirement to include the bases for these sections with but not as part of the technical specifications was added and an addition to the definition of an unreviewed safety question found in 10CFR50.59 was made. This addition made it an unreviewed safety question to make a change to the facility or procedures described in the safety analysis report that reduced a margin of safety that was defined in any of the new technical specification bases. Thus the AEC had a new tool to protect margins of safety which they considered "sacred" to the extent that they did not wish to allow them to be reduced without explicit AEC review and approval. This tool, of course, was to define such a margin of safety in the new technical specification Bases now required by 10CFR50.36. All of these changes were proposed in a single Federal Register notice (Vol. 31, No. 158, pp. 10891-10894) and implemented in a single Federal Register notice (Vol. 33, No. 244, pp. 18610-18612)."

Previous NRC Guidance:

NRC Inspection Procedure 37001, "10CFR50.59 Safety Evaluation Program" acknowledged that "[b]ecause precise meanings of the USQ criteria are not provided in Section 50.59, the thresholds for USQ involvement will be interpreted differently from licensee to licensee."ⁱⁱⁱ

Further, the NRC has not endorsed NSAC-125, "Guidelines for 10CFR50.59 Safety Evaluations," because "the guidelines described in NSAC-125 go beyond what is required by 10CFR50.59 in certain respects. Thus, the Commission does not believe that the

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guidelines are appropriate for endorsement as regulatory guidance."^{iv} In the letter from B. Grimes (NRC) to W. Rasin (NEI) dated April 22, 1996, the NRC restates its position on the NSAC-125 guidance as follows: "[s]ince the publication of NSAC-125 in 1989, the staff has attempted to prepare a position that would endorse (with comment) NSAC-125. These efforts were not successful due in large part to the issues relating to understanding the meaning of the rule language discussed below." The letter then continues and addresses the issue of interpretation of "margins of safety." The letter states: "[i]n practice, questions arise about what is 'a margin of safety' and which margins of safety are 'defined in the basis for any TS.' If a specific statement about a particular parameter or 'margin' is not explicitly included in any TS Basis section, the degree to which other documents (SAR, staff safety evaluation report, etc.) must be consulted to determine whether there are margins which define the underlying basis for any TS requirements that may be affected by the change is unclear."^v

More importantly, within the NRC Inspection Manual, Part 9900, the NRC states explicitly that "[t]he NSAC-125 guidance is broader than the rule regarding where a licensee must look to find a margin of safety in that it recommends looking beyond the TS Bases."^{vi}

Conclusion:

Determining whether an unreviewed safety question exists provides a means to determine when NRC review and approval is necessary, but does not necessarily dictate whether an activity is safe. When 10CFR50.59, defines an unreviewed safety question, the margin of safety is restricted to those margins of safety that are defined within the confines of the bases section(s) of the technical specifications.

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References:

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- i NRC letter to NEI dated April 22, 1996, Enclosure 3, NRC Inspection Manual, Part 9900 dated April 9, 1996. Section C, "Current Staff Practices".
 - ii References:
 - 1) 10CFR50.59, WHY WE HAVE IT - WHAT IT SAYS for the American Nuclear Society/European Nuclear Society, 1988 International Conference, November 1, 1988, Washington, D.C., prepared by Daniel Williams, P.E.
 - 2) Letter from B. Grimes (NRC) to W. Rasin (NEI) dated April 22, 1996, Table 1.
 - 3) Federal Register notices; Vol. 31, No. 158, pp. 10891-10894 and Vol. 33, No. 244, pp. 18610-18612.
 - iii NRC Inspection Procedure 37001, "10CFR50.59 Safety Evaluation Program," dated 12/29/92, paragraph 03.01.c.2.
 - iv NRC Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors.
 - v Letter from B. Grimes (NRC) to W. Rasin (NEI) dated April 22, 1996, Background Section.
 - vi NRC Inspection Manual, Part 9900 dated April 9, 1996. Section C, "Margin of Safety".